EXHIBIT G

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Shirley Freeman, et al., Plaintiffs, vs. ETHICON, INC., et al., Defendants.	Case No. 2:12-cv-00490

TVT-SECUR
Tuesday, March 8, 2016
- - -

Deposition of SUZANNE PARISIAN, M.D., held at Marriott Tempe at the Buttes, 2000 West Westcourt Way, Tempe, Arizona, commencing at 1:35 p.m., on the above date, before Alisa Smith, Arizona Certified Court Reporter.

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SUZANNE PARISIAN, M.D.,
the witness herein, having been first duly sworn by the Certified Court Reporter, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. GAGE:

Q. Good afternoon, Dr. Parisian.

A. Good afternoon.

Q. Before we get started with the Q and As, and just so that the reader of this transcript will know what has transpired, we are together in Phoenix, Arizona. It is in the afternoon.

And this morning, from approximately 9 a.m. local time until noon or somewhat after noon, I deposed you concerning your opinions in the federal multidistrict litigation concerning the Prolift+M device; correct?

A. Yes, sir.

Q. And during that deposition, I asked you a pretty significant number of questions about your background, training, experience, what you have and have not done; correct?

A. Yes, sir.

Q. And you would agree with me that nothing has changed in the intervening hour since we concluded

that deposition and the start of this deposition that would cause your answers to change to the vast majority of those questions; correct?

A. Yes, sir.

Q. So can we agree that it would be in our -- everyone's best interest of time management for me not to re-ask those questions?

A. Yes, sir.

Q. Okay. And I would refer the reader of the depo to the Prolift+M transcript of Dr. Parisian's testimony in the event that they wish to read that information.

(Whereupon, Exhibit No. 1 was marked for identification.)

BY MR. GAGE:

Q. All right. Dr. Parisian, the first document I'll hand you is the Notice to Take Deposition of Suzanne Parisian, which is marked as Exhibit 1.

You've seen this document; correct?

A. This morning for the Prolift. I hadn't seen it before.

Q. I think that's actually a combined depo notice that pertains to both Prolift+M, and then somewhere in there, it also pertains to TVT-Secur.

A. Okay. No, I hadn't seen it before.

Q. And just so the record is clear, we're here this afternoon not to discuss your Prolift+M opinions but your TVT-Secur opinions?

A. Yes, sir. And there was another depo for that once before too.

Q. Yes.

And the depo you're referring to is the deposition in the Garcia versus Ethicon case; correct?

A. Yes, sir.

Q. And I believe that deposition occurred in February 2015; correct?

A. Sometime in 2015, yes, sir.

Q. Have you had a chance to read that deposition?

A. I don't recall that I have.

Q. Okay.

MR. JONES: Real quick, William. I won't take much of your time. And just for the record, we do have an agreement that you will not be covering the topics that were already covered in that deposition that was taken of Dr. Parisian in February 2015. And today's deposition will be limited to topics that are new and outside of the topics that were covered in that deposition.

MR. GAGE: Yes, with the understanding -- with two -- two caveats. One is plaintiffs' counsel, obviously, then agrees that that deposition in the Garcia case can be used as though it were taken in the federal MDL case.

MR. JONES: I don't think we're going to have any objection against that.

MR. GAGE: Okay. And then secondly, there are a few places where I'll need to ask questions that would be repetitive of what was asked in February of 2015, but it is being asked to determine if the witness has done anything since --

MR. JONES: Sure.

MR. GAGE: -- February 2015. So -- but --

MR. JONES: But a general agreement.

MR. GAGE: Yeah, general agreement that we don't intend to be duplicative of what you were deposed about in February 2015.

MR. JONES: And just to add to that, there were -- you did e-mail some specific topics that you thought maybe it was a rough roadmap of what you believe to be the topics that you felt were new, or maybe a better word, not covered in the February 2015 deposition that you had the right to

ask about.

And if we need to refer to that at any point, that might help, but generally speaking, not going to cover same ground that was covered in the February 2015 depo.

MR. GAGE: Yeah, generally speaking. I mean, I did send you the -- I think there was a question -- when I sent that e-mail, there was a question as to whether I should even be permitted to take any deposition of her on TVT-Secur.

So what I did was I went through the report of Dr. Parisian in the MDL case and compared it to the disclosure and the depo in Garcia in order to assure myself there really was some differences, because I was concerned maybe there were no differences, in which case my position would be much more difficult.

And by illustration, I showed you -- I e-mailed and sent six topics, but trust me, you and I are generally on the same agreement. I don't want -- I've got limited time.

MR. JONES: When we get there, we'll dig into it.

MR. GAGE: Exactly, exactly. I've got limited time with her, and I need to focus on things

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that she's not --
MR. JONES: Absolutely.
MR. GAGE: It's good for me to find the stuff that she hasn't been asked about.
(Whereupon, Exhibit No. 2 was marked for identification.)
BY MR. GAGE:
Q. All right. So, Dr. Parisian, I'm going to hand you what I have marked as Exhibit No. 2, and I believe this to be your TVT-Secur opinion in the MDL case, but please look that over and confirm that that is correct.
A. Yes, sir. Yes, it is.
(Whereupon, Exhibit No. 3 was marked for identification.)
BY MR. GAGE:
Q. All right. And, Dr. Parisian, I'll hand you what's been marked as Deposition Exhibit No. 3 to your TVT-Secur deposition. It also happens to be marked Deposition Exhibit No. 4 to the Prolift+M deposition.
This is your current CV. Is that correct?
A. Yes, sir.
Q. And it is current and accurate, and there's nothing more to add or subtract from it; correct?

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A. Yes, sir.
(Whereupon, Exhibit No. 4 was marked for identification.)
BY MR. GAGE:
Q. I'll also hand you Exhibit No. 4, which is also marked as Exhibit No. 5 in the Prolift+M case today, and this is the legal testimony history of Dr. Parisian. Is that correct?
A. Yes, sir.
Q. And that's a complete and accurate listing of your legal history over -- for the time period that's stated in that report; correct?
A. Correct. It won't have Prolift+M on it.
Q. I'm sorry?
A. It won't have Prolift+M on it yet in terms of the depo.
Q. Which was taken this morning?
A. Right.
(Whereupon, Exhibit No. 5 was marked for identification.)
BY MR. GAGE:
Q. And then, Dr. Parisian, I want to mark as Exhibit 5 --
A. Well, the red one is 4, so that would be 5, yeah.

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Q. All right. This will be Parisian Exhibit 5 to your TVT-Secur deposition, and I understand this to be the list of documents provided or identified for review in the above-referenced lawsuit. Is that correct?
A. That's what it states, yes, sir.
Q. This is what we often refer to as the reliance list.
Can you confirm that for me, that that is yours for the Secur case?
A. Yes, sir.
Q. All right. Dr. Parisian, with regard to your TVT-Secur report in the MDL, who typed that up?
A. I did.
Q. Can you tell me approximately when you started work on that report and when you completed work on it?
A. No, sir. I don't have the -- I can't do that without the bill in front of me. I'll get you the bill.
Q. All right. Let me just ask you, we know that you were deposed in the Garcia case in February of 2015; correct?
A. Right. Um-hmm, yes.
Q. That was about TVT-Secur; right?

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A. Right, but there was no report written at that time.
Q. And that was the first and only -- well, that was the first case in which you had been designated as a TVT-Secur expert. Is that right?
A. That's right.
Q. Before that case, had you been retained to provide opinions on any Ethicon mesh device?
A. No. No, I hadn't.
Q. And can you -- and is it -- it is fair to say that you were retained by the plaintiffs in the MDL in the year 2015 to provide an expert opinion on TVT-Secur? Is that correct?
A. Technically, I wasn't employed by the MDL to start with. I was with Clark, Love & Hutson, just one case.
Q. All right. So in the Garcia case, that's a Clark --
A. Right.
Q. -- Clark, Love case; correct?
A. Right.
Q. And who retained you in the MDL for TVT-Secur?
A. I sort of got transferred, and I think Wagstaff & Cartmell are the people that are the

office I'm supposed to touch base with.
Q. Okay. So Clark, Love possibly got in touch with Wagstaff & Cartmell, and that's how you got involved in the MDL litigation for TVT-Secur?
A. Something like that. I'm not sure if they were in the MDL. I don't know. Somehow I ended up in the MDL in a wave.
Q. And would that transfer have occurred after your deposition in Garcia?
A. Yes.
Q. Not looking for specific dates. Just ballpark.
Do you know when you first -- well, strike that.
Is it fair to say that all the opinions you intend to offer in this case are contained either in your expert report that we've already marked or in your TVT-Secur deposition in the Garcia case or in the disclosure in the Garcia case?
A. Yes. As far as I know, I've tried to capture them all in those three documents.
Q. All right. I don't have an extra copy of your TVT-Secur deposition in Garcia or an extra clean copy of your disclosure, so I'm not going to mark those as exhibits.

But I'm explaining to whoever may read this deposition, we all know what those documents are. It was one disclosure that you filed -- or that was filed on your behalf in Garcia about TVT-Secur, and then of course there's one deposition transcript, the actual date of which was February 12, 2015?
MR. JONES: Correct.
And we can get to the bottom of this later, but my memory is that there might have been a supplemental disclosure filed as well.
MR. GAGE: Yes.
BY MR. GAGE:
Q. Dr. Parisian, do you recall filing a supplemental disclosure in the TVT -- for TVT-Secur in the Garcia case?
A. I don't -- I don't recall that. Did I do that?
MR. JONES: And that's my memory that there was one filed in court. Again, if you have it, if you don't have it, we can get to the bottom of it later but --
MR. GAGE: Okay.
MR. JONES: -- my memory is that there was a supplemental designation filed in that case that's on that docket.

MR. GAGE: Okay. All right. So I don't have a copy of that.
MR. JONES: It may have been marked -- I don't think it was marked at her deposition, though.
MR. GAGE: Okay. I do -- it seems like I recall some discussion of it at her deposition, though. I could be mistaken.
BY MR. GAGE:
Q. All right. So I've marked as Exhibit 5 here for this deposition a notebook, a black binder called TVMS docket at the top, and then below it, it says, "TVT Secur."
And it says, "This belongs" -- on the cover it says, "This belongs to Suzanne Parisian, MD," and I've marked that as Exhibit 5.
Do you see that?
A. Yes, sir.
Q. And you gave that notebook to me or your counsel before the start of this deposition; correct?
A. Correct. And I --
MR. JONES: Just for the record, that was also gave to you, Ethicon, at the February 2015 deposition as well.

MR. GAGE: That was going to be my very next question.
MR. JONES: Sorry.
MR. GAGE: That's all right.
THE WITNESS: Yes, it's the same document that was given to you.
BY MR. GAGE:
Q. All right. So I'll ask the question.
Dr. Parisian, this notebook that's been marked as Exhibit 5 at this deposition is exactly the same notebook that was given to Ethicon's counsel in the -- in your deposition in the Garcia case back in February 2015?
A. Yes, sir.
Q. Okay. And this notebook contains a number of highlights in it. I see, I think, a few handwritten comments here and there. I certainly see a lot of stickies -- yellow, purple, orange, red.
Is it fair to say that all of the markings on all the documents contained within Exhibit 5 are your markings?
A. Yes.
Q. And you're the one that affixed the stickies to the various documents?

A. Correct.
Q. Do the colors of the stickies or their organization or placing have any significance?
A. No.
Q. All right.
A. And they were on at the other depo too, the stickies.
Q. Okay. Good.
We'll ask to have a copy made, if we don't already have this from the prior depo, complete with the highlighting and the stickies.
A. Yes.
Q. Dr. Parisian, there is a -- we have to make a change here. Let's get this very clear on the record.
The black notebook entitled, "TVMS Docket, TVT Secur," the one that you and I have just been discussing, we're going to have to mark that Exhibit 6 --
A. Okay.
Q. -- not Exhibit 5.
A. Okay.
Q. That was my mistake. So we're going to mark that Exhibit 6, and I'm going to draw through the 5 and mark the No. 6 on that exhibit sticker that's

attached to the front of that notebook.
(Whereupon, Exhibit No. 6 was marked for identification.)
BY MR. GAGE:
Q. So, Dr. Parisian, Exhibit 5 to this deposition is your reliance list for your federal MDL TVT-Secur report; correct?
A. I think so. I did mention this morning that I saw Dr. Miklos' report, and I don't know if -- I don't see it on the reliance list. And so that would be a report that I have seen --
Q. Okay.
A. -- because you said, "Oh, that's for TVT-Secur."
Q. Right.
So -- and we'll -- we'll figure this out through the course of the next several questions, but what I'm -- did you prepare the reliance list that's marked as Exhibit 5?
A. No.
Q. Do you know who prepared that?
A. No. No, I don't know who prepared it.
Q. Have you ever seen that before?
A. You know, I don't remember if that was at the same -- at the depo that we had for Garcia, the

same list.
Q. Well, it's got a federal heading at the top of it --
A. Right, right.
Q. -- and by that time in February of 2015, you had not been retained to provide an expert opinion in the federal court proceeding for TVT-Secur, had you?
A. Correct. They can change the heading. I'm talking about the list.
Q. Gotcha.
A. There should have been a reliance list at the depo. That's all.
Q. Got it.
Do you have a reliance list from Garcia other than just merely the contents of that notebook that's marked as Exhibit 6?
A. No.
Q. If I were to -- if I were to try to understand the universe of documents that you have reviewed for your TVT-Secur opinions, is it correct to say that there are two sources? One is the reliance list that's marked as Exhibit 5, and the second would be the notebook that's marked as Exhibit 6?

MR. JONES: Objection.
THE WITNESS: They should be similar, the book and the reliance list.
BY MR. GAGE:
Q. And you're speaking of Exhibit 5 and 6?
A. Five and six, yeah.
Q. Have you looked to see to the extent to which they're similar?
A. No, no. But this was sent to me all put like this, so I assumed that the person who put the reliance list knew what they sent to me.
Q. Okay. And when you were tapping your finger, you were tapping your finger on the notebook marked as Exhibit 6?
A. Six, yes. And I'm just saying about five, I just never checked because I knew it was coming from someone else who was sending me a reliance list.
Q. All right. So Exhibit No. 6 which is the notebook, was that supplied to you in the form in which it sits on this desk right now, i.e., in a hard copy notebook?
A. Yes, sir. Stickies and all that are mine, but it was in a book.
Q. Was that sent to you by the Clark --
A. Yes.

Q. -- Hutson firm?
A. Yes.
Q. Did you receive from that firm any disks or other electronic copies of documents for you to review?
A. I don't recall. I didn't check it. This was -- this was the bulk of what I used, so I don't recall a CD. I don't -- I didn't look at my computer for it because I knew that this was what I had used primarily for the report.
Q. Is it possible that you have additional TVT-Secur documents on your computer that aren't in the notebook?
MR. JONES: Objection.
THE WITNESS: They would have been things that are not confidential documents other than depos. I don't know if there's depos on it.
That would be the only thing that would be confidential, because I would go and pull stuff up and put it on the computer.
BY MR. GAGE:
Q. All right. Do you have a list, or can you provide me with a list of the depos that you would have -- well, strike that.
On the reliance list, on the first page,

there's a section that calls -- that attempts to itemize the depositions that have been provided to you.
Do you see that?
A. Yes, sir.
Q. Do you know if that list on page 1 accurately matches the depositions you actually have reviewed and/or received for purposes of your TVT-Secur opinion?
A. I don't know. I can do the same thing that I'm going to do for the Prolift+M and go look and see what's on my hard drive.
Q. Okay. Good. That's where I was headed.
I was going to ask you through your counsel if you would be willing to give us an itemization. I don't need anything fancy, but just an itemization that bears your signature so we know it has been approved by you --
A. Right.
Q. -- that would identify any depositions that you may have received and/or reviewed for purposes of your TVT-Secur opinion and which don't already appear on Exhibit 5.
A. Yes.
Q. And to your -- when I deposed you earlier

this morning on Prolift+M, you handed me several exhibit -- several stacks of additional documents that you had reviewed in conjunction with your Prolift+M documents -- Prolift+M opinions.
Do you have any additional documents that you would like to hand me with regard to your TVT-Secur opinions that you have either gathered on your own or have received from some other source?
A. Yes. Here they are.
Q. All right. So --
MR. JONES: Just for clarification, I think the 2008 FDA big document that was marked as Exhibit 6 earlier, I think that would probably also be applicable to her TVT-Secur.
THE WITNESS: You mean the 522?
MR. JONES: Yeah.
MR. GAGE: Okay. So I'm glad you mentioned that, Nate.
MR. JONES: Maybe not so much the other one, the reclassification.
MR. GAGE: All right. So why don't we -- again, Nate, we don't ever know who's going to be reading this stuff. It could be, you know -- and you and I may remember it, but the people who are going to come along after us.

THE WITNESS: Yeah. The reclassification and the instruments, that would be another one. Do you have that? I think so.
MR. GAGE: I'll pull that one too.
MR. JONES: I think it's underneath your hand.
(Whereupon, Exhibit No. 7 was marked for identification.)
BY MR. GAGE:
Q. So, Dr. Parisian, I'm handing you a stack of documents that you handed me this morning in conjunction with your Prolift+M which I understand to be documents that you obtained from counsel that pertain to FDA communications about surgical mesh. Is that correct?
A. One of them does. This one here does. This one here is the -- the -- yeah, there you go.
So, yes, Exhibit 7 would be what we had from this morning as Exhibit 6, and it's the FDA inter-discussion about what they were going to do with mesh.
Q. Okay. And are you talking about Exhibit 7 to this deposition, the stack of FDA documents, those are documents -- well, let me ask it like this: Are those documents that you reviewed --

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first reviewed after you wrote your TVT-Secur report?
A. Yes.
Q. So those are just additional materials upon which you may refer as you give your opinions on TVT-Secur?
A. Right. And it's basically the internal discussion of the FDA.
Q. And I think we discussed it during the Prolift+M deposition that it is at least your understanding that those documents were obtained by plaintiffs' counsel through some form of request to the FDA. Is that correct?
A. They look like the type received from a FOIA request. They're redacted.
Q. And FOIA is F-O-I-A, Freedom of Information Act, request?
A. Yes, sir.
(Whereupon, Exhibit No. 8 was marked for identification.)
BY MR. GAGE:
Q. All right. And then the other document that we need to mark is another stack of documents that you handed me during the Prolift+M deposition this morning where the title of it is "Reclassification

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of Urogynecologic Surgical Mesh Instrumentation, FDA Questions." We marked it as deposition Exhibit 7 to your Prolift+M. It will now be deposition Exhibit No. 8 to your TVT-Secur.
A. Yes.
Q. And is that the stack of documents that -- that you handed me this morning from the Prolift+M?
A. Yes, sir.
Q. All right. And, Dr. Parisian, those -- I see some -- some highlighting and a sticker on that.
Is that your highlighting and your sticker?
A. Yes, sir. Yes, sir. It's mine.
Q. All right. And if I remember correctly, those were documents that you actually pulled, found yourself. Is that correct?
A. Yes, sir.
Q. All right. Are there any additional documents or reports that you have reviewed and/or relied upon in conjunction with your Prolift+M expert report in the federal MDL?
A. You mean the TVT-Secur?
Q. I'm sorry. Let me rephrase it. I knew that was going to happen.
Dr. Parisian, apart from the documents that we've already covered during this deposition, are

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there any other documents or materials that you reviewed or relied upon in preparing your expert report in the federal MDL for TVT-Secur?
A. Well, I brought the Amended Miklos' report. I brought also, if you look in there, the 2015 TVT label even though --
Q. Oh, I'm sorry. These documents in front of me were part of what you handed me. Okay.
So let's mark those real quick.
(Whereupon, Exhibit No. 9 was marked for identification.)
BY MR. GAGE:
Q. So, Dr. Parisian, I'm handing you a document that I've marked as Exhibit No. 9, which is the documents you handed me a few moments ago.
Can you tell me what that is?
A. This is -- I believe it's the 2015 -- yeah, the Ethicon label. It's the most recent one I can find.
Q. And that one has been changed from prior versions; correct?
A. Yes, sir.
Q. Is it -- is it an adequate label?
A. No, it's not an adequate label. It's a better label, but it's not an adequate label because

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it's still not very specific to TVT. It's not anything to do with TVT-S. It's just TVT, but it is the current one right now.
Q. All right. Now, T- -- and you couldn't put out a 2015 label for TVT-S because it's no longer on the market?
A. That's right. It's off the market.
Q. All right. And where did you get that label from?
A. I asked for it, and I got it from counsel yesterday.
Q. All right. Are there any other documents that you asked counsel to provide you?
A. Yes. The one that you had from the FDA, that one we've all discussed. The other things all there are mine.
Q. All right. And the ones -- what you're referring to are the documents that are still in my hand that I haven't marked as exhibits yet, and we're going to go through those.
But your -- your -- your statement with regard to these documents still in my hand are -- these are documents that --
A. They were in my folder, and I don't think you had them necessarily, so I was giving them to

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you to be complete.
Q. Got it. All right. So let me look at this really quick.
(Whereupon, Exhibit No. 10 was marked for identification.)
BY MR. GAGE:
Q. Doctor, I'm handing you Parisian Exhibit 10. What is that document, which you gave to me earlier?
A. Actually, this is for Prolift. It should have been for Prolift. Yeah, these are all documents that I thought I had given to you this morning that I didn't, yeah. So they really should go with the one we had this morning.
Q. All right. So --
A. There is one document that applies to both of these in there, and that's the Ethicon references off of their Web site as to medical literature. And that would have been what Ethicon would give a physician for the medical literature.
But like you said, the product TVT is off the market, TVT-S, Secur, and the rest are there for pelvic organ prolapse.
Q. All right. I'm going to --
MR. GAGE: Let's just go off the record

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for a second.
(Discussion off the record.)
BY MR. GAGE:
Q. So TVT-Secur -- so now that we're back in the TVT-Secur deposition, Dr. Parisian, you handed me a collection of documents which we were going through after the deposition started.
One of them is an Amended Expert Report of Dr. John Miklos in the Garcia case; correct?
A. Yes, sir.
(By agreement of the parties, the court reporter was instructed after the deposition to mark the Amended Expert Report of John Miklos in the Garcia case as Exhibit 10A to the deposition in order to correct a mistake made by defense counsel in marking two different exhibits as Exhibit 10 during the deposition.)
(Whereupon, Exhibit No. 10A was marked for identification.)
BY MR. GAGE:
Q. All right. And that was a document that you had at the time you wrote -- or at the time that you were deposed in the Garcia case; correct?
A. Yes, sir.
Q. And what was the significance, if any, of

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this report to your opinions on TVT-Secur?
A. The physician opinions, because that's what he talks about, and, also -- what was the significance? I believe when I had the Garcia, I talked about it, and I didn't see it listed on the reliance list, and so I wanted to make sure you had it.
Q. Okay. Have you for purposes of your MDL report received any physician expert reports?
A. No.
Q. Have you received any expert reports from anyone?
A. No.
Q. All right.
MR. GAGE: I'm going to mark as a collective exhibit a number of documents that you handed me that appear to pertain to patents. And this is going to be Exhibit 11.
(Whereupon, Exhibit No. 11 was marked for identification.)
BY MR. GAGE:
Q. All right. Dr. Parisian, you handed me after the depo started the documents that are in collective Exhibit No. 11.
Can you tell me what those are and what

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their significance are to your opinions in the MDL?
A. I knew one of your questions was about the TVT-S that you were going to ask me about microporous versus heavy, and so I was trying to find the definition of PROLENE.
And so that was what I actually went and got this one patent from, and it's not the patent as much as it defines what PROLENE is, and so that's why I have that patent, and I put a yellow sticky there, and it's highlighted.
Q. So the yellow highlighting and sticky are your marks?
A. Right.
Q. Did you actually get that between the time that we concluded the Prolift+M deposition and this afternoon?
A. No, no. I had it. I got it last night because I knew that was one of your questions.
Q. When you said, "I knew that that was one of your questions," you were just speculating that I was going to ask you that?
A. Yes, yes.
Q. Okay. And it turns out that I did ask you that?
A. Yes, and I had gone and done my homework and

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I want -- because it's hard to have a definition of PROLENE and so -- because, you know, it's a pre-amendment product, and it's been out there, and so I've been trying to find something that would define it to look at, you know, the weight and the porosity.

So I found something, and so -- and then as I went and looked for the patent, I went and got the trademarks, just to kind of get -- put me on the right track as time-wise, so that's what this is about.

Q. Is it your understanding that the TVT-Secur is made of the same mesh that's contained within the documents marked as Exhibit 11?

A. It's not -- it's made of the same -- no. This is -- this is different. The mesh that it's made out of is the PROLENE here where it's talking about the standard PROLENE. So it's made of this mesh, which is the PROLENE.

Q. All right. And when you say -- you're pointing to page 4 of this document --

A. Right.

Q. -- that references PROLENE mesh manufactured by Ethicon, Inc., and it gives an average flexibility, burst strength, pore size, and

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thickness; correct?

A. Correct.

And so the company is defining what PROLENE is so I wanted to -- because it's kind of hard to pin it down, and so I believe TVT-Secur is made out of PROLENE, which is your basic garden variety PROLENE, and so -- and it's 49 percent porosity and trying to -- so I was trying to hone in on it.

Q. Okay. And I think you and I were discussing this earlier, and we got a little confused.

You understand there's PROLENE material and there's PROLENE mesh?

A. Sure, I know about PROLENE suture. I mean, yes, I can go through PROLENE, but it's all from the resin, which is a polypropylene resin that they can make it into suture, they can make it into fibers, and they extrude it and make it into mesh.

Q. Okay. So for purposes of the TVT-Secur opinion that you have, is it your understanding, for example, that the average flexibility, the burst strength, the pore size, and the thickness of the TVT-Secur is that which is found on page 4 of this document that's marked as Exhibit 11?

MR. JONES: Objection.

THE WITNESS: You know, I don't know.

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I haven't seen a specification where the company defines PROLENE, but I was trying to put my finger on something that the company defines.

BY MR. GAGE:

Q. Okay. So --

A. It's in their patent defining what PROLENE is, and so that's where I will -- you know, I would just say in terms of the porosity and stuff.

So I have no doubt that the TVT-S is made out of PROLENE, and PROLENE has been on the market since the '70s, before -- before it was even 510(k) cleared.

(Whereupon, Exhibit No. 12 was marked for identification.)

BY MR. GAGE:

Q. All right. Dr. Parisian, I'm handing you a collection of documents that were already tabbed as collective Exhibit 12.

Can you tell me what those documents are and what is their significance, if any, to your TVT-Secur opinion?

A. Well, it's showing different -- if you're manufacturing, you want to get mesh, polypropylene filament mesh. These are the types of documents -- one of them is a guidance document. I don't know if

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you're familiar with that.

But these are mesh patterns. See how the mesh -- so people can get it woven, and they have different -- I was trying to hone in on the PROLENE. Nobody calls one of these PROLENE, but you can look at the mesh pattern and try to figure out the size.

Q. Were you able to determine, from looking at Exhibit 12, which of the various lines of data pertain to the mesh in TVT-Secur, if any?

A. This -- this one here looks the most like it, but I'm not the mesh expert. I mean, that would be like 100 weight. This is the right weight, thickness, so it would be something like in this here.

Q. And the line that you're referring to is the line that has PPKM 601?

A. Yeah. But, again, I'm not your mesh expert, so . . .

Q. All right. And then -- and did you gather this document on your own?

A. Yes, sir.

Q. Was this just for your own general guideline information?

A. Yes, sir.

Q. I take it you don't have any -- you're not

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rendering any specific opinions about this document?
A. No.
Q. Okay. And then since it is a composite exhibit, it's got something from surgicalmesh.com behind it.
A. Right. And so I was just going and looking at sources of polypropylene mesh. This is the guidance document which is -- we haven't discussed that yet.
Q. All right. So the final document contained within composite Exhibit 12 is a guidance for preparation of premarket notification application for surgical mesh dated March 2, 1999; right?
A. Right.
Q. And that's an FDA guidance; correct?
A. That's right.
Q. Did that ever become final?
A. You know, I don't think it has. I've never seen one after 1999. I know they've had a thing for IDEs for SUI devices, and they're going to do a PMA, but I don't think I've seen a later version.
Q. Again, the reason you handed me that document is because it was a document that you went and got on your own -- is that correct? --
A. Yes, sir.

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Q. -- the guidance?
(Whereupon, Exhibit No. 13 was marked for identification.)
BY MR. GAGE:
Q. All right. Then the final exhibit is Exhibit No. 13. It's a single sheet of paper, at the top of which it says, "Microbiological Safety."
Dr. Parisian, what is that document?
A. This is the ETHISORB Dura Patch. I was looking at the -- there's some microscopic information about it.
Q. What is the significance of that document, if any, to your TVT-Secur opinion?
A. Well, TVT uses the -- that patch. That's what the arms are is the ETHISORB Dura Patch. So I was looking for documents about the Dura Patch.
Q. Well, I should be perhaps more pointed.
Is there anything specific in that document that impacts your opinion one way or the other about the safety or efficacy of the TVT-Secur?
A. Not anything other than what I've written in my report, but I'm giving it to you to be complete.
(Whereupon, Exhibit No. 14 was marked for identification.)
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BY MR. GAGE:
Q. All right. And then the final document -- I thought I was finished, but I had one more -- Parisian Exhibit No. 14.
Dr. Parisian, that document has what as its title?
A. 510(k) Sterility Review Guidance. There's actually a guidance document that you can get. It's the same document.
Q. All right. What is the significance, if any, of that document to your TVT-Secur opinions in the MDL?
A. Well, the 1997 document says that the reviewer is not going to review the sterility information. They're going to leave that until a facility inspection. So it was kind of a change in policy because FDA actually had looked at sterility data up until '97. In '97 they stopped.
Q. Why?
A. You know, I don't know why they did. They stopped because I think they wanted to cut cost. It takes a lot for a reviewer, and it -- they wanted to speed up the process, and they decided that they would check sterility information when they did a good manufacturing practices quality systems

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inspection.
Q. Did you find this document on your own?
A. I have it -- that one I don't think I did, but I have that document at home.
Q. Where did you get this?
A. It was in my papers here. I don't know where it came from, but there is a real guidance document that looks like a guidance document that goes with that, and I have it. But I don't know why, and that was just floating in these documents here.
Q. You mentioned something about inspections?
A. Yes, sir.
Q. Does FDA have the power or the ability to conduct inspections of manufacturers of 510(k) cleared devices?
A. Well, when? I mean, FDA has the authority to inspect manufacturing facilities. They're regulatory or required to do it every two years, but they're not making that. They're supposed to be inspecting.
But are you talking about at the time of the 510(k)?
Q. No.
Let's talk about Ethicon and the TVT-Secur.

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A. Okay.
Q. During the time that the TVT-Secur was on the market, did FDA have the legal authority to conduct an inspection of Ethicon's manufacturing facilities and/or documents concerning TVT-Secur?
MR. JONES: Objection.
THE WITNESS: The FDA does have the legal authority, but it's at the -- it's at the pleasure of the company in terms of what they want to show the FDA.
FDA doesn't just get cart blanche over, "We want to see all your documents." They can ask for them, and the manufacturer can say yes or no.
But do they have the authority to inspect? Yes, the FDA does. Do they have the resources to inspect? Not much. That's where they're falling behind.
BY MR. GAGE:
Q. When they conduct an inspection, what do they inspect?
A. Usually pick maybe one or two devices as kind of exemplary type of things that they look at, and they're looking for systemic error or some kind of an issue. And so they don't inspect everything. They don't have time or resources to inspect

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everything. That's when they come to a facility inspection.
Sometimes in the documents I saw for the FDA work committee, they actually were sending inspectors in to try to get information about the -- so that's kind of a directed inspection where they'll have a district office person go in and get some documents that they're asking for.
The FDA has fairly limited ability to inspect. They can, but they don't.
Q. Just with respect to TVT-Secur and Ethicon, did FDA ever conduct any inspections?
A. I don't know. In the document that I saw from the FDA in 2007, 2008, they were talking about going and doing an inspection to get information of all manufacturers, so I don't know.
Q. Did any other regulatory body conduct any inspections or audits of Ethicon for its pelvic mesh devices while TVT-Secur was on the market?
A. You mean in the United States?
Q. In any country.
A. I'm not aware of them inspecting. I know that they were having to deal with other countries outside the United States, but I'm not aware of anything specific.

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Q. Do regulatory bodies outside of the United States have the authority to conduct inspections or audits of a medical device manufacturer, such as Ethicon, and a device like the TVT-Secur?
MR. JONES: Objection.
THE WITNESS: They have the authority. I mean, the thing is resources. Because now we're even using -- in the United States, we're using foreign inspectors to try to catch -- catch up on our inspecting of facilities. You know, they're trying to harmonize them and so they can inspect.
But, you know, I don't -- I don't think -- and I didn't discuss any of the inspections in my report.
BY MR. GAGE:
Q. During the time period when TVT-Secur was on the market, if FDA conducted an inspection or an audit, could they ask to see any document the company may have with regard to TVT-Secur, or can they only ask for a subset of documents?
MR. JONES: Objection.
THE WITNESS: They can ask. The company doesn't have to provide them. Usually they will put it in their inspection report if the company refused, so the company is allowed to

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refuse.
And every inspection for a medical device company is announced, so it's not like the FDA surprises them. They know they're coming. They know what they're going to ask for. And it's -- and it's supposed to be at the convenience of the company.
BY MR. GAGE:
Q. Dr. Parisian, do you consider your TVT-Secur report to be complete?
A. At this moment in time, I don't have anything else that I want to add to it.
Q. All right. So you have no current plans to supplement the opinions. Is that correct?
A. As far as I know, yes, sir.
Q. Do you have any plans to do any additional work with regard to TVT-Secur?
A. No, sir. I have not been requested to do anything else.
Q. Is there any information that you're waiting on relating to TVT-Secur which might cause you to change or alter the opinions in your report?
A. No.
Q. Have you asked plaintiffs' counsel for any documents or other papers that you may need with

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regard to TVT-Secur?
A. No.
Q. All right. Dr. Parisian, going back to your reliance list, am I correct that Clark, Love gave you the notebook that's been attached as Exhibit 6? Correct?
A. Yes, sir.
Q. Did you get any additional documents from anyone other than the ones that we've already discussed and marked?
A. No, sir.
Q. So is it -- is it a true statement that your MDL report on TVT-Secur was based on the documents that we have marked already as exhibits with the understanding that you're going to go back and look to see if there were some additional documents or depositions that were not contained either in your reliance list or in the notebook marked Exhibit 6?
A. Yes.
MR. JONES: Objection.
THE WITNESS: Yes, sir.
MR. GAGE: What's the objection?
MR. JONES: The exhibits to the deposition, I don't think you included that in the deposition. Her testimony, the multiple

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disclosures, we still haven't got to the bottom of the supplemental disclosure issue.
I think he's made a reference that it wasn't actually filed or served.
MR. GAGE: Oh, the supplemental?
MR. JONES: I just want to make sure that the supplemental disclosure, her testimony, the exhibits that were included, the prior deposition of TVT-Secur, to me, it's just -- there's a broader universe than what you included in your question.
MR. GAGE: That's good to know.
BY MR. GAGE:
Q. So if we include the documents that counsel just referenced, then, Dr. Parisian, is it correct to say that would be the entirety of the universe of the documents that you have reviewed and/or relied upon in preparing your MDL Secur opinion with the exception of the documents that you are going to go back and check and deposition exhibits?
MR. JONES: And objection.
Do you want me to explain the objection?
MR. GAGE: Please do.
MR. JONES: The objection is, the issue is for me, you know, she's worked on mesh litigation

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for years. She's worked on mesh litigation outside of TVT-Secur. The reliance list and the materials I just referenced are limited to her TVT-Secur materials.
That doesn't mean that materials she's reviewed for Prolift+M or, you know, other mesh litigation doesn't generally support her opinions. So that's the distinction for me.
I don't want to get into a spot where you're trying to hammer down and box her into this one specific issue. Oh, wait, she talked for 30, you know, pages, or she reviewed this, you know, article. It just didn't appear on her TVT-Secur list because it was on another list, Prolift+M, or -- you know, we get into the issue of you go back -- years back to the medical school education. That's my issue, that she's reviewed stuff for -- what? -- four, five years now -- three, four, five years on surgical mesh and transvaginal mesh specifically.
And those obviously are going to impact her opinions generally. They might not specifically relate to TVT-Secur, but she's going to rely on that expertise that she's formed over the past four years working on mesh.

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MR. GAGE: Yeah, and I understand that. And I think my questions are much more directed toward learning what documents did you receive for the purpose of drafting a TVT-Secur report?
MR. JONES: Okay. And then -- and then if you want to break it up even more to internal documents, then that makes it somewhat easier, because then, you know, if it's related to the Ethicon internal documents on TVT-Secur, then that, to me, breaks it up and makes it more specific.
Again, she's reviewed an internal document that may not be specifically about TVT-Secur. But we were just going back and forth about PROLENE and what exactly does PROLENE mean. Well, it might not be on her TVT-Secur list, a document that speaks to PROLENE. But that's generally going to support her opinions in a TVT-Secur report if you're going to ask her about, well, what is PROLENE?
BY MR. GAGE:
Q. Well, let me ask you this: She's got two reliance lists in the -- in Ethicon cases, either the Prolift+M or the TVT-Secur reliance list; correct?
A. Yes, sir.

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Q. And we covered exhaustively today what you have and have not reviewed with regard to Prolift+M; correct?
A. We covered what I reviewed, yes.
Q. Right.
With regard to TVT-Secur and your federal opinion, I assume you reviewed some, if not all, of the documents regarding Prolift+M while you were working on your TVT-Secur opinion.
Is that a correct statement?
A. Well, they're all cumulative. I think that's what he's trying to say.
Q. And I'm not suggesting they're not cumulative. I'm just trying to get an understanding of, so, I've got a basket of documents that were -- that were -- they fall into two categories. For Prolift+M, they're documents that were either sent to you or you got them yourself?
A. Yes.
Q. For TVT-Secur, there's a basket of documents that were either sent to you or you got yourself?
A. Right.
Q. You don't have any other reports for any other Prolift or any other Ethicon devices?
A. That's correct.

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MR. JONES: And just object.
The issue for me, you're saying documents. In your documents, you're including literature, regulations, internal documents, records, whatever.
I mean, you're not meaning internal documents, internal Ethicon documents?
MR. GAGE: No. I'm being broader than that because I think no matter how broadly you categorize them, they still fall into one of those two buckets. I either got them alone or I got them from somebody else.
THE WITNESS: Or I know about the issues anyway.
MR. JONES: Or she already knew it.
MR. GAGE: Right.
BY MR. GAGE:
Q. But if it's a document, you can't -- you got to specifically have it in your hands. You either had to go get it or somebody had to give it to you.
A. Right.
Q. It has to be one of those two things.
A. But like we were talking about polypropylene, and I know polypropylene from lots of other issues that has nothing to do with vaginal

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mesh. So, I mean, I know about poly and we use --
Q. And I'm not trying to limit your knowledge to just the documents you received. I'm trying to drive at whether there is a universe, a group, a list, a cache, a collection of documents --
A. Right.
Q. -- that you have reviewed for your Ethicon work, be it Prolift+M or TVT-Secur, beyond the documents that we have marked as exhibits either to the Prolift+M deposition or to the TVT-Secur deposition.
That's really where I'm just trying to get at.
MR. JONES: Understanding she's worked on additional mesh litigation related to transvaginal mesh products.
MR. GAGE: Yes.
BY MR. GAGE:
Q. All right. So I'll ask this question: Have you reviewed Ethicon documents for other mesh litigation that does not appear on your reliance list for Prolift+M or TVT-Secur?
MR. JONES: Ethicon internal corporate documents?
MR. GAGE: Yes.

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THE WITNESS: I looked at Ethicon documents. I don't know if they're internal. Like TVT, I looked at -- somewhere along the line, I've seen the 510(k) for TVT and some of the interaction back and forth between the FDA. And I don't think it would have been in an Ethicon litigation, but there were documents that other people had.
So I've seen other Ethicon documents, TVT-O, TVT, so -- but I'm not involved in those cases at this point in time. And so, you know -- but I have seen those documents, but I haven't seen the Ethicon version of the -- I've seen --
Because other manufacturers would go get Ethicon documents, and they're usually FYI documents; right? They've been redacted. So I have seen Ethicon documents but not necessarily internal documents.
BY MR. GAGE:
Q. Okay. So now let me -- let me limit your -- let me change the question.
A. Okay.
Q. Let's talk about only the documents that you have received from lawyers who were making claims against Ethicon. I don't want to talk at all about documents that maybe the AMS lawyers gave you. I

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want to talk about the documents that the lawyers representing the plaintiffs in the Ethicon litigation have given you.

Do you have any group or list of documents for either Prolift+M or TVT-Secur other than the ones that you have shared with us today in either the Prolift+M deposition or the TVT-Secur deposition?

A. No. Other than I'm going to go look at the depos and see what I have.

Q. That's what I needed to --

A. So I've given you my file.

Q. Okay. Now, with regard to the medical literature pertinent to your opinions -- strike that.

Regarding the medical opinions regarding TVT-Secur, is it correct to say that the literature that you have reviewed with regard to TVT-Secur is either found in the notebook that's attached as Exhibit 6 or in your reliance list that we've marked, or is otherwise already marked as one of the exhibits in -- in -- to this deposition?

A. I'm looking to see if the --

MR. JONES: Objection.

THE WITNESS: -- Cochrane report is in

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here because the Cochrane report I reviewed for something, and so I've reviewed the Cochrane report even before I got involved in this, and so in terms of TVT-Secur, that's in there.

BY MR. GAGE:

Q. All right. So let me ask you this: When -- when -- is there a list of documents -- see, I understand -- for example, I think what you're saying is like with Cochrane review, you were given that document -- or were you given that document, or did you go find it on your own?

A. I went and found it, but it wasn't for TVT-Secur. It was looking at mini slings, so I was looking at mini slings, and the TVT-Secur is the one that's in the Cochrane report. There's a lot of discussion about it.

Q. Okay. So that document, the Cochrane review, is not going to be in Exhibit 6?

A. No, but I had seen it before.

Q. I understand.

It's not in Exhibit 6; right?

A. I don't -- I don't know. It may be. That's why I was looking in this report, because I mean, that is relevant to TVT-Secur, and then the FDA document when they were talking about it yesterday,

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the one I have that, Exhibit 6 or 7 --

Q. Yes.

A. -- they were talking about the Cochrane report. They didn't have the whole Cochrane report in it. And so that -- I don't see that it's listed on my list, and so that would be something else that's in there in terms of TVT-Secur.

Q. Do you have a list of documents that fall into that category?

And just so that we're clear, the category is --

MR. JONES: What is the category?

MR. GAGE: The category is, "The list of documents that I'm relying upon that form the basis for my TVT-Secur opinions which do not appear in my reliance list or in Exhibit 6."

MR. JONES: And what's the scope of that?

MR. GAGE: Well, she was able to specifically recall very acutely the -- the --

THE WITNESS: Cochrane review?

BY MR. GAGE:

Q. -- the Cochrane review, and so I would ask you, do you have a list or a -- either a written list or a mental list of, "Here are 8 or 10 or 15 or

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20 or 100 documents that I know are pertinent to TVT-Secur but which don't appear on my reliance list or in this notebook"?

A. That's the only one I can really think of because that's a biggie, but I had read that with nothing to do with TVT-Secur. I was looking at single incision slings, and so that was something that -- that TVT-Secur is in that.

Q. Did you do a PubMed search for TVT-Secur?

A. I don't think I did.

Q. Did you do a functional equivalent of a PubMed research? I understand you can do it by using PubMed or some other service.

Did you do either a PubMed or some other functionally equivalent medical literature search for TVT-Secur?

A. I don't recall that I did. I don't recall that I -- I ever did because TVT -- I mean, TVT has been involved in so many other cases, I didn't do a search for TVT-Secur.

Q. And I take it you have already produced what you would consider to be your complete file to us -- to me today?

A. Yes, sir, other than the depos that I didn't print out.

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Q. Have you ever spoken with anyone who you understand to be an expert in the mesh litigation with regard to your TVT-Secur opinions?
A. No.
Q. With regard to your documents and invoices reflecting compensation regarding TVT-Secur, where is that?
A. I didn't bring them. I didn't see the depo notice, so I didn't bring them.
Q. Shame on you.
A. I know.
Q. I hereby mark that witness's answer in the event you guys complain one bit if one of my experts doesn't bring it. So noted says the plaintiffs' lawyers.
A. Well, normally when I see the notice, I pull everything out. I didn't see a notice, so I didn't do it.
Q. Can we -- can I ask you to provide that documentation to Nate, and, Nate, will you agree to provide that?
MR. JONES: Absolutely. It's coming. And I'll look for the post-it note binder at the next deposition from the defense experts --
MR. GAGE: Thank you.

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MR. JONES: -- which I know will not be produced.
MR. GAGE: Oh, of course you know it will.
I'll tell you what. What we probably ought to do, if we can agree to do this, can we go ahead and agree -- and, Madam Court Reporter, you might say you don't want to do this, but let's see if y'all will agree to it.
Can we agree to mark that document that reflects her compensation on her MDL TVT-Secur work as the next exhibit to this deposition, so that when you produce it to me --
MR. JONES: It will be part of the record?
MR. GAGE: -- can you go ahead and send it to this court reporter so she can make it part of the record so that it carries forward in perpetuity with the depo, and you and I don't have to keep trying to find it later on?
MR. JONES: I think -- I think that's something I will try my best to do. Absolutely.
MR. GAGE: All right. And let's make sure --
MR. JONES: I don't see a problem with

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that. Not knowing really what logistically is required, what I'm getting myself into. Generally, yes.
MR. GAGE: If you want to later, you know, object or call me and say, I now have a reason for it, I'll understand. I'm not going to go nuts on you, but I do think we're entitled to it. And I do think it would be very helpful if we attach that document, even though we haven't seen it, as the next exhibit. What Exhibit No. would that be, Madam Court Reporter?
The parties have agreed, subject to Nate's perhaps needing to reconsider, as Exhibit 15 the document that Dr. Parisian will provide to Nate that reflects her compensation for the work that she's done with regard to TVT-Secur in the MDL.
(Whereupon, Exhibit No. 15 was later marked for identification.)
BY MR. GAGE:
Q. Dr. Parisian, do you have any recollection of how much time you would have spent on the TVT-Secur work in the MDL?
A. No, I don't. I don't, because I know that you had the bill from Garcia. I produced the bill for that, and then the depo, and then I don't know

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what -- because we're only talking about the report, so I don't know what that was.
Q. What is your hourly rate?
A. $400 an hour for in my office. $600 an hour for this today.
Q. Deposition?
A. Yes, sir. And testimony in court.
Q. Is $600 a day?
A. No. An hour.
Q. I'm sorry. $600 an hour for trial testimony?
A. Yes, sir.
Q. All right. Do you know how much time you spent reviewing documents for your TVT-Secur work as opposed to actually writing your TVT-Secur opinion?
A. No. Because, see, that's a protracted one in that I've done disclosure, and there was time for that, so you should have had the bill from the disclosure, when we came out with, you know, my review time, and so then when it came to writing the report, it really -- I had already made opinions and stuff, so it didn't take that long to write the report for the MDL.
Q. When you -- you were obviously asked sometime in 2015 to write the report for the MDL;

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right?
A. Right.
Q. As I understand it, because of your prior work in Garcia and because the documents were essentially the same, is that a correct statement that the documents you reviewed and relied upon in Garcia are essentially the same?
A. Yes.
Q. And I used the word "essentially." I'm not trying to trap you and say identically --
A. Right.
Q. -- but they're essentially the same --
A. Right.
Q. -- as between Garcia and the MDL report?
A. Right.
Q. Have you published any of the opinions you're offering about TVT-Secur?
A. No.
Q. Have you spoken with any scientist, engineer, or medical doctor regarding your Secur opinions?
A. No.
Q. Is it correct to say that you developed your TVT-Secur opinions specifically for litigation and not for a research project or formal study?

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A. Yes.
Q. And as we discussed at your Prolift+M deposition, you don't have case-specific opinions that you intend to render with regard to any particular TVT-Secur patient; correct?
A. I'm not their medical causation person.
Q. And I think you testified in your Prolift+M deposition that the extent of your case-specific opinions would be a review of the information necessary for you to determine issues, such as the date on which a particular patient may have been implanted, in order to determine what perhaps might be the applicable patient brochure and/or where to place that particular plaintiff's implant date in against the backdrop of some regulatory timeline. Is that correct?
A. In terms of the timeline Ethicon was dealing with in terms of what they knew, when, yeah. When you go to court -- the reports are written general, and so when you go to court, you have to have a more honed in time period so that it's relevant to the patient.
And so I usually use their time frame in order to kind of hone in my regulatory opinions and my opinions of the physician as to what's going on.

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But it's not causation, per se. It's just limiting the world to the time that's relevant to that patient.
Q. Right.
And so, for example, you don't review a patient -- a particular patient's medical records and then render a medical opinion as to the cause of that particular plaintiff's alleged injuries, for example?
A. Yes. I try to keep the amount of medical records review low. I will pay attention to what the physician says as to what he knew and what the labeling should have been because that feeds into the actions that the company could have taken to notify that doctor, so that's part of my pattern too.
MR. GAGE: And, Nate, can we have the same stipulation from counsel as you gave us in the Prolift+M deposition, that you do not intend to put up Dr. Parisian as a case-specific expert apart from the discussion that we just had with her?
MR. JONES: Yeah, yes.
BY MR. GAGE:
Q. Dr. Parisian, am I correct you do not have any manufacturing defect opinions with regard to

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TVT-Secur?
A. Naming individual lot to lot, no, I don't have any. Obviously, I talk about design in terms of adequacy of design and follow-up and complaint handling, but a specific lot defect, no, because I don't even know who the patients are. How can I have --
Q. But once you find out who the specific patient is, it's not your -- it's not your role to look at a specific lot and then make a medical or render a medical causation opinion. Is that correct?
A. I've been asked to do that sometimes, but I'm not -- I'm not planning on doing it because oftentimes we don't have the lot information on these things, and I need to have the -- I need to have manufacturing records.
If I get the manufacturing records, I may look at it. Sometimes it pops up, but I don't know of one right now.
Q. To date, have you reviewed any TVT-Secur manufacturing records?
A. No.
Q. And you're not here as a representative of FDA; correct?

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A. That is correct.
Q. You're not here speaking on behalf of the FDA; correct?
A. That is correct.
Q. FDA has not reviewed or endorsed any of your opinions in this case?
A. That is correct.
Q. Have you ever spoken with anyone from FDA regarding your Secur opinions?
A. No.
Q. Have you ever called or written to FDA about any of your Secur opinions?
A. No.
Q. While you were at the FDA, did you ever have any involvement with TVT-Secur?
A. No.
Q. Any involvement with any of the predicates to TVT-Secur?
A. I don't think so. I mean, you're -- I don't think so. I mean, I was in urological devices, but I didn't see anything there. And the surgical mesh, I was involved with some surgical mesh, but nothing specific to the urological use. I came after -- I left before ProtoGen and before TVT.
Q. Dr. Parisian, I asked you this morning in

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your Prolift+M deposition a number of questions about board certification, staff privileges, credentials at hospitals and studies that you may or may not have done with regard to surgical mesh.
Is it fair to say that the answers you gave in the deposition this morning would be translatable to this deposition such that I do not have to re-ask those?
A. Yes, sir. I have not changed in that period of time.
Q. Is it correct that you never did any kind of mechanical testing of the mesh in TVT-Secur?
A. Yes.
Q. You did not do any type of testing or measurements of the mesh in TVT-Secur?
A. Correct.
Q. And that's not something you would do in your normal practice. Is that correct?
A. Correct. I would normally look at the data and not test it.
Q. Do you believe you have the requisite education, training, and experience to counsel a patient about treatment options for stress urinary incontinence?
A. You know, I probably could as a physician,

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but I wouldn't. I don't think that I would be the right person to counsel somebody about that.
Q. Why not?
A. I wouldn't counsel a patient about treatment of their urological problems. I mean, there are certain things I do know. I mean, patients will ask me, "What have you seen in terms of litigation and stuff?" I wouldn't do that.
That's -- that's a patient and a physician that talk about that.
Q. If someone came to you wanting to counsel with you about treatment options for SUI, what would you tell them?
A. I would tell them that -- what would I tell them? I would tell them Kegel exercises, what I know, and pumpkin seed. You know, other things that are noninvasive, and maybe push them on to a urogynecologist, something like that. That's not mine.
I mean, everybody has to have their own -- I'm not a -- I'm not a practicing physician right now in terms of counseling patients what to do.
Q. Have you ever seen a TVT-Secur implanted in the body?
A. No.

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Q. And by that, I mean have you ever watched a TVT-Secur being implanted in someone?
A. No.
Q. Have you ever watched a video of a TVT-Secur procedure?
A. No.
Q. Have you ever held a TVT-Secur in your hand?
A. No.
Q. Have you ever been in the same room as a TVT-Secur device?
MR. JONES: Sorry. When you get to a stopping point, break --
THE WITNESS: No.
MR. GAGE: Let's take a stopping point.
MR. JONES: Thanks.
(Recess taken.)
BY MR. GAGE:
Q. All right. Dr. Parisian, do you agree that you do not have the requisite education, training, and experience to implant a TVT-Secur?
A. Yeah.
Q. And do you agree that you have not had the requisite education, training, and experience to counsel a patient about the risks and benefits of TVT-Secur?

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A. Yeah. I wouldn't -- I wouldn't do that. That was not what I would do.
Q. Would you agree that there are patients who have had TVT-Secur who have had no complications?
A. I don't know.
Q. Would you agree that there are patients who have had a good experience with TVT-Secur?
A. I -- I don't know. I don't know what the patient experience is.
Q. Would you agree that there are women who have had a TVT-Secur placed where it has been a safe and effective device for them?
MR. JONES: Objection.
THE WITNESS: It's the same answer. I don't know.
BY MR. GAGE:
Q. Do you know if there are pelvic floor surgeons in the United States who believe the TVT-Secur was safe and effective?
A. I don't know.
Q. If there were such doctors, would you disagree with them on that point?
A. Since I'm not implanting, I would let them talk about it, but I'm sure there's other people that would talk about the other side too, so I don't

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know.
Q. Have you written a draft IFU or a patient brochure for TVT-Secur that is adequate in your opinion?
A. No, I have not written a draft.
Q. Do you have any list or document or PowerPoint slides or anything like that that would purport to be a listing of words that need to be either specifically added to the TVT IFU -- TVT-Secur IFU patient brochure or need to be taken out of either the TVT-Secur IFU or patient brochure in order to make them adequate?
A. No, I don't have a list.
Q. Have you ever spoken with a doctor who has implanted a TVT-Secur?
A. No.
Q. Have you ever spoken to any pelvic floor surgeon about the TVT-Secur IFU?
A. No.
Q. Have you read the depositions of any doctors who have implanted TVT-Secur?
A. With Ms. Garcia I did. I forget who her doctor was, but there were depositions from the doctor.
Q. Any others beyond that?

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A. No.
Q. Did that deposition inform your MDL opinion in any way?
A. It fed into it. I don't reference it at all in terms of that, but you asked me if I read a deposition, yes, I read one.
Q. When you say it fed -- the reading of the deposition fed into your MDL report, do you mean -- was there anything specific or in particular about that deposition that caused you to change or caused you to write any one of your MDL opinions in a specific way, or do you just mean to say, hey, it's part of the knowledge base that I had at the time when I sat down to write the TVT-Secur report?
A. It's part of the knowledge base.
Q. Did you review any professional education materials from Ethicon with regard to TVT-Secur?
A. I don't believe I did. I'm trying to remember if I put in my report whether I referenced any marketing.
You have a list of -- in my report, you would have the documents that I've reviewed in terms of the marketing of the company.
Q. Would it be fair to say that -- well, strike that.

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And, Doctor, I want to ask you a question. Do you draw any distinction between Ethicon sponsored professional education and Ethicon marketing?
A. They can overlap because sometimes marketing will be in charge of the professional education, and so they can overlap.
Q. What is your understanding of what the professional education training for TVT-Secur entailed?
A. Well, they would identify a physician that would be like usually a key opinion later or trainer, someone that knows the product, and then they would usually have a class full of doctors who want to learn about it. And they would probably use cadavers, and they would oftentimes do pigs or some other animal, and they would teach them how to do the technique.
Q. Is that a good thing?
A. Is that a good thing? It's what is done in terms of the procedure. That's not a bad thing.
The thing is that the design of the product actually had some flaws to begin with, and you want to design a product that would behave the way it's supposed to. And this one had some major problems

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in terms of the design.
Q. Are you critical of the Ethicon-sponsored professional education program for TVT-Secur?
A. Not in the program. The issue is that the physicians weren't really learning about the potential risks and how difficult it was to do the procedure. So it's more with the contents.
But to have a program, no, I'm not critical of their having a program.
Q. Do you recall what documents you reviewed, if any, to determine what training and what risks were covered in the Ethicon-sponsored TVT-Secur professional education program?
A. I have -- I looked at various company documents. I didn't look at a single course. I looked at -- and I think if you go to Opinion 7 where I talk about the commercial use of the device, those are the documents that I looked at in there.
And some of it would be company documents, the cookbooks, the tips and tricks, and -- but not necessarily a coursebook. Okay? So it would be under the Section B, and it would go 1 through 10.
Q. Do you have a recollection of looking at any specific documents that were generated as a result of the Ethicon-sponsored professional education for

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TVT-Secur?
A. Not the coursework. That's why I say I was looking at things where they're internally talking about what they're going to put in the course. That's primarily what's there.
Q. If those documents existed, would you want to see them?
A. I don't know if I would be the person who would see them. It seems like it would be more of a surgeon that would see them in terms of who's done the procedure.
I would look at them in terms of the way I was -- in terms of FDA's training in looking at labeling, but I think it would really be a surgeon that would probably be addressing what the contents are.
Q. Dr. Parisian, let me ask you this: If Ethicon did not specifically disclose a risk of the TVT-Secur in the IFU but specifically disclosed the risk of -- that risk of TVT-Secur in another form, would that impact at all your opinions?
A. Well, I mean, you may not have every -- you're saying they may not have had everything in the IFU. They may have had some in the training materials.

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And, yes, if you took it together as all labeling, and you took the sales reps as all labeling, but they had been trained to teach this, then, yes, you could get away with that, in that their information, but it has to be accurate. It has to be fair and balanced in terms of the risk potential.
Q. Did you -- I'm sorry.
A. No, go ahead.
Q. Did you undertake to do a comprehensive analysis of the TVT-Secur IFU, the TVT-Secur Ethicon-sponsored Prof. Ed, and the TVT-Secur patient brochure and other potential documents in order to come up with like an exhaustive list of every risk that the company warned about with regard to Secur?
MR. JONES: Objection.
THE WITNESS: I looked at the company documents. The company documents, you're talking about different risks that I didn't see reflected in the IFU or the training information or the patient brochure, so the company documents actually are the primary.
And the information that you should see being given to the physician in some way should be

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coming from the information that the company has. And that's why my report is broken down talking about what the company knew internally, as opposed to the labeling and the training materials.
BY MR. GAGE:
Q. Did you look at any Ethicon-sponsored peer reviewed published medical literature to see whether that was a source of additional risk information for TVT-Secur?
A. I did see some TVT-Secur in it. The problem with it is that it didn't tend to have a fair balance in terms of the risk.
I mean, the FDA, when they went and they did a literature search, said that the information about transvaginal mesh wasn't adequate, that there hadn't been studies that had been done long enough with the success value criteria.
Admittedly, those were for SUI and POP, not single incision. But the literature that I saw was similar, in that the TVT-Secur didn't have long enough follow-up, didn't have good valid end points. So there are complications -- problems with the literature that I did see.
Q. Okay. Did you attempt, for example -- well, strike that.

Did you look at the TVT-Secur published medical literature in order to do a comparison between the risks that were disclosed in that literature versus the risks disclosed in either the IFU or the brochure?

A. No. Because I'm looking at the internal documents, which actually had more information about risks than I saw in the IFU or the patient brochure.

Patient brochure has almost no risk information. So, you know, you really need to look at what the company is saying. The known, knowable information, as opposed to the information that's being provided.

(Whereupon, Exhibit No. 16 was marked for identification.)

BY MR. GAGE:

Q. Doctor, I'm handing you a document marked Parisian Exhibit No. 16.

Have you ever seen that document before?

A. I don't know. All these ladies start looking alike in terms of these. I think I may have.

When was this one published? 2008.

Q. Now, just to be clear, Dr. Parisian, did you get that 2008 date from the -- kind of the trademark

on the very last page of this document?

A. Yes, sir.

Q. Okay.

A. Is that not correct?

Q. I don't know. I just wanted to know --

MR. AYLSTOCK: Excellent question.

BY MR. GAGE:

Q. You said -- you threw out the date 2008. I just didn't know where you got it from, and then I just wanted to confirm, is that where you're getting the date from?

A. That's where I'm getting the date from.

Q. Okay.

A. Look, the same people are in this one.

Q. Would it be -- would it be correct to say that in order to answer the question whether you have reviewed this specific document before you wrote your TVT-Secur MDL report, I would need to look at either the folder of documents we've marked as an exhibit or your reliance list?

MR. JONES: Or you can just look at her report. That discusses these items.

THE WITNESS: Yeah, because I'm looking to see, because it's on page 99. What did I talk about?

BY MR. GAGE:

Q. Well, let me ask a question.

A. Patient brochures.

MR. GAGE: Nate, this is probably a good discussion for you and me to have.

Have -- has counsel for plaintiff done a comparison between her TVT-Secur expert report and her reliance list to make sure those two match up, or should I treat them as to --

MR. JONES: What do you mean "match up"?

MR. GAGE: That she may cite to documents in her report that don't appear on the reliance list?

MR. JONES: Have I gone through that?

MR. GAGE: Yes.

MR. JONES: No. That's your job.

THE WITNESS: This -- this is --

MR. JONES: Unless you want to do that for us on --

THE WITNESS: This is in my report, this document.

MR. GAGE: This exact document?

THE WITNESS: Yeah.

MR. JONES: So here's the deal.

Earlier this morning when you were going back and forth about the reliance list, things that you were saying, hey -- and I objected, and I said, hey, I don't think that's accurate.

They're listed in her report and so, one, you know, she talks about them specifically in her report, and then you're going to the reliance list. I'm sure you had someone look at, run it -- or on a computer look at, well, that ETH.MESH number isn't on here. Well, maybe that ETH.MESH number is listed in her report.

That is the same brochure listed under a ETH.MESH in the reliance list. I don't know. I haven't gone through and done that.

But I know that the brochure and IFUs are discussed in her report, and I think specifically -- I actually don't think it's this specific ETH.MESH number, but I know the specific TVT brochure is discussed in her report. But that's the long way of saying no to your answer -- to the question you asked earlier.

MR. GAGE: I've been burned before at trial many times with experts saying, "Oh, yeah. I reviewed and relied on this. It's not on any document or listing that I've given you, but you

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should have asked the right question at the depo," which is why I'm just -- I go overboard on asking those questions.

MR. JONES: I get it. I think this one is talked about in her report.

THE WITNESS: Yeah.

BY MR. GAGE:

Q. And so, Dr. Parisian, do you -- do you believe this is the document that you have specifically reviewed and discussed in your report?

A. Yes, sir.

Q. Okay.

A. Yes, sir.

Q. And on page -- I'll call it page 13 of the exhibit.

A. Right.

Q. And you'll see the page numbers there. You see what those page numbers are?

A. Yeah. In my report, I talk about page 11 and page 13 from this document.

Q. All right. And I may be misquoting you. If I am, then the record will correct me, and the question will be stricken.

But I thought I heard you say the patient brochure did not disclose any of the risks?

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A. Yes.

Q. Okay. So we see on page 13 a paragraph that says, "What are the risks?" And it says, "All surgical procedures present some risks."

Do you agree with that?

A. Yes, but that's not telling them about this procedure.

Q. All right. "Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury."

Do you see that?

A. Yes, sir.

Q. Now, is it your opinion that a patient contemplating a TVT-Secur implant who reads this patient brochure would not recognize those as risks of the TVT-Secur?

A. No. They're thinking it's risks of the surgery. All surgical procedures present some risks, so they're talking about the acute phase of the surgery. They're not talking about the device. They're talking about the surgery.

So if a patient was reading that, that's what they would take that home as, oh, okay. If I have my surgery, this is my potential risk. But

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they're not saying, you have chronic risks, too, that are going to occur. It's not just something immediately postop.

Q. Have you discussed this brochure with any TVT-Secur patient?

A. No.

Q. Have you conducted any surveys or studies of TVT-Secur patients as to their understanding of the reading of the TVT-Secur patient brochure?

A. No. But this is based on my training and experience, looking at labeling as a physician and an FDA person who's been trained to do that.

Q. Have you conducted a -- or have you -- I asked it -- I think I've already asked this, but I can't remember.

Have you asked any pelvic floor surgeon about the TVT-Secur patient brochure?

A. No.

Q. Have you conducted a survey or study of pelvic floor surgeons about what they would understand the risks to be of the TVT-Secur procedure from reading the TVT-Secur patient brochure?

A. What a physician would get out of it or what a patient?

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Q. Physician.

A. Physicians, no, I haven't, but this is not made for a physician. It's made for a patient.

Q. If a physician read this?

A. Right. Does it say anything about the chronic complications? No.

Q. Let me -- let me ask the question. Okay, Dr. Parisian?

If a physician read this patient brochure and they read the sentence, "Complications associated with the procedure include injury to blood vessels of the pelvis," is it your testimony that a physician could only interpret that to mean that it is related to the procedure, not the mesh, and that it only can be acute and not chronic?

A. Yeah.

Q. Okay. Difficulty urinating?

A. Right. Postop, they have difficulty urinating, so this is --

Q. Let me pose the question.

So a physician reading the phrase "difficulty urinating" could only interpret that to mean it is a risk of the procedure, not mesh, and it could only be acute and not chronic?

MR. AYLSTOCK: Objection to form.

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MR. JONES: Objection.
THE WITNESS: That's the problem with the way this is written. It talks about, "All surgical procedures present some risk," and so when it's talking about complications associated with the procedure, they're not saying with the device, with the implant. You're saying "with the procedure."
So a surgeon would be reading this -- and a patient which is more important because this is for a patient -- is that these things would be associated with the procedure; not the device.
And so these are things that occur from that, not -- not the TVT-Secur.
BY MR. GAGE:
Q. All right. And as to the remainder of that sentence that says "pain, scarring, pain with intercourse, bladder and bowel injury," would the same hold true in the sense that it is your opinion that a surgeon reading those words would associate those complications only with the procedure and not with the mesh and would understand them to be only acute and not chronic?
MR. AYLSTOCK: Objection to the form.
MR. JONES: Objection.
THE WITNESS: Well, this is written for

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a woman. It's not written for a surgeon. But there's nothing here that says these are chronic. These conditions can occur postop, that they can occur a long-term away.
So the way it's written is that these complications would be something that a woman would expect to see in the immediate postop period.
BY MR. GAGE:
Q. But my question was about a doctor, so could you --
A. Well, he's the doctor. Remember, doctors oftentimes don't see patients after the postop period. They may see them maybe in a week or two weeks and may never see them again.
See, this is saying that in your postop course, you may see something like this, but it's not saying that these women would have a chronic problem.
MR. GAGE: Could you read back the original question?
MR. AYLSTOCK: Before you do that, just for the record, Dr. Parisian was questioned extensively on the TVT-Secur patient brochure in her prior deposition, so I just want to note that.
I'm not saying you can't ask another

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question about it, but we are getting into replowing old ground at this time.
MR. GAGE: I gotcha. I understand your position. All right.
So could you re-ask the question?
(Requested portion was read by the Court Reporter.)
MR. AYLSTOCK: Objection to form.
THE WITNESS: And the answer is yes --
BY MR. GAGE:
Q. Okay.
A. -- which is what I said.
Q. So the next sentence says, "There's also a risk of the mesh material becoming exposed."
A. Um-hmm.
Q. Do you see that?
A. Um-hmm.
Q. What does that communicate to a surgeon?
A. Postoperatively you could have exposure of the mesh.
Q. What does it communicate to a patient?
A. To a patient? That you can have complications right after your surgery.
Q. Is it your opinion that that sentence about the risk of the mesh material becoming exposed

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refers only to immediate postop and not in the long-term?
MR. AYLSTOCK: Objection to form.
THE WITNESS: That's the way it's written. It's talking about that, and then exposure may require treatment. What does that mean to a patient? Well, it could mean -- it doesn't say, you may need surgery to have the thing removed. It just says "treatment."
A physician -- if you go back to your physician, it could mean something in the office, as opposed to you might need to take this thing out which -- and you might need revision surgery. That's not being conveyed there.
BY MR. GAGE:
Q. Did TVT-Secur -- or did surgeons who implant -- strike that.
Did surgeons who implanted TVT-Secur know that the mesh could erode before implanting?
A. You know, every surgeon that's going to have a case, we're going to have the surgeon saying what he knew. And the question is erode, whether they needed to know that they're going to have surgery, that they had to take it out, how frequently it was eroding. All those things they didn't know.

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And most of them will testify that they haven't known, or they didn't know that in terms of the Garcia case that -- so each surgeon for every case is going to talk about what they knew.

Q. Did you conduct any survey or any study of either surgeons or literature in order to ascertain what risks of TVT-Secur surgeons were aware of generally when the device first came on the market?

A. No. That would have been -- I looked at the sales documents, and so we actually had the sales documents. What they're telling the doctor, that this was going to be less invasive and that it was going to be -- because you only had one -- one incision, and that you could do either the egg shaped or the U shaped. And so they're telling the doctor that it's very easy, one incision, and that doesn't go along with the product.

So, no, I didn't. But looking at this, what are the risks, this is written for a patient, and it's not talking about the long-term risks. It's only talking about the risks of the surgery.

MR. JONES: I need to make a record real quick on the brochure and the general agreement that we hashed out prior to the depo and at the beginning of the depo it was confirmed that you

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weren't going to cover the same ground as the Garcia case and the Garcia deposition that was taken in February 2015.

And you said we'd both do our best jobs, so here's my best job of ensuring that doesn't happen.

This brochure that you just marked as an exhibit and asked her, you know, quite a few questions on was actually -- she was actually questioned about it in her prior deposition.

A TVT-Secur brochure was actually introduced as an exhibit at that prior deposition. In fact, it looks like it's the same brochure that you just used at this deposition.

So if we can do our best to not do that again --

MR. GAGE: I will.

MR. JONES: -- I would really appreciate that.

MR. GAGE: If you'll notice, what provoked it was the witness said, "There is no risk information in the patient brochure."

I immediately reached over and got the brochure, which I wasn't intending to use with her. I couldn't let that statement go completely.

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I mean, I know it was covered, but I was surprised to hear her say that, and that's why I did it.

MR. JONES: Okay. And my response is that I think you could have used what was already covered in the prior deposition, then.

THE WITNESS: And I still hold that opinion. And the risk information is still inadequate. There's nothing here to tell the woman about the chronic long-term risks that she's going to have with this device.

MR. GAGE: And we don't need to debate it further.

MR. JONES: It's the record.

BY MR. GAGE:

Q. The reason, Dr. Parisian, that I posed all these questions to you is I think your testimony was, there is no, meaning zero, risk information in the patient brochure, and that is what I could not let go unaddressed, and that's why I felt it was necessary.

I do understand, admit, and recognize that you've always taken the position that the patient brochure is inadequate, but that was the first time I heard you take the position --

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MR. JONES: And she talks about it in her report, and it's addressed in her report under risk, so if we can move on. But that's just -- my point is if we can try our best not to, at the very least, cover the exact same exhibits that were used at the prior deposition --

MR. GAGE: I understand.

MR. JONES: -- that would be great.

BY MR. GAGE:

Q. So, Dr. Parisian, what's the risk of erosion with TVT-Secur known to the medical community in 2006?

A. 2006? Well, it wasn't known in terms of 2008 in terms of the risk of erosion. FDA was trying to call for the information, even for the single incision sling, so I don't think it was known.

That it could occur, yes, but the risk and how frequently it was occurring, the severity of it, no, that was not known.

And that was what the -- all the stuff happened in 2008 for the FDA to try to get some information about that for women.

Q. Do you know what the earliest date in the published medical literature is where the risk of

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erosion was discussed or identified as a risk of stress urinary incontinence mesh?
A. Well, I know with ProtoGen it was discussed back in '98.
Q. What about the risk of chronic dyspareunia with stress urinary incontinence mesh? Do you know when that risk was first discussed in the public medical literature?
A. Well, that also was associated with ProtoGen. The issue is that it was discussed in the literature so, therefore, it was noticed for Ethicon to know that this was a potential risk in anything they designed.
Q. Do you know when the risk of chronic pain as a risk of stress urinary incontinence mesh was first discussed in the public medical literature?
A. I don't know when chronic pain was.
Q. I'm sorry?
A. I don't know the date for chronic pain.
Q. Did you discuss any sort of survey or analysis of the published medical literature to determine what risks, if any, of stress urinary incontinence mesh were known to the medical community as of, say, 2005 or 2006?
A. I've looked at various literature. No, I

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did not do a search. I mean, I've looked at literature since the '90s, so, no, I did not do a conducted search to look for when they knew certain things.
I go back to the ProtoGen because I know those were the risks that it was getting removed from the market. So, therefore, to me, that's notice for the industry that there was an issue with ProtoGen, and it was a potential unacceptable risk.
Q. Dr. Parisian, is chronic pain with intercourse a risk of non-mesh stress urinary incontinence surgery?
A. I think we talked about that earlier today. It depends, I mean, because in women who have the non-mesh surgery, you know, the traditional things, they usually are chronic patients anyway. They've had problems. They've had multiple surgeries, and so who knows. I don't know.
The question is, would chronic dyspareunia have occurred to a woman who had minimal symptoms, got an elective transvaginal mesh procedure, would that be something you would expect in that patient? No.
Q. All right. And just to be clear, the questions we talked about this morning, I posed

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these questions in the context of pelvic organ prolapse, and now I'm going to pose these questions in the context of stress urinary incontinence.
So they may sound the same as this morning, but they are -- they are different because I'm going from pelvic organ prolapse to stress urinary incontinence.
A. Right.
And the answer basically is the same, though, that a woman who would go in and get a surgery from a urologist for stress urinary incontinence before these transvaginal mesh usually is a person that's had chronic problems and symptoms, and so you didn't just lightly go in and have these procedures done.
So when the transvaginal mesh came, the issue was you had a brand new population, women that stress urinary incontinence was all she had, and that was just a symptom that may have been uncomfortable when she was at a class in yoga. And so some of these women didn't have much.
So in terms of risk versus benefit, they shouldn't have any kind of risk of chronic dyspareunia when they really had very little benefit that they were going to get from these transvaginal

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mesh.
Q. All right. So I think the answer to the question -- the question as posed was, is chronic pain during intercourse a potential risk of non-mesh SUI surgery, and I think your answer was yes. Is that correct?
A. In the caveat that you had two totally different populations. You had a population that would have gone to surgery, traditional surgery, versus a population with minimal symptoms as a rule for SUI. And so you're comparing apples and oranges.
You have a specific group, yes, they could have chronic dyspareunia, but they are a different starting group than the group that got the transvaginal mesh.
Q. Well, I understand that, and I'm not asking you to weigh the relative risks as between the mesh group and the non-mesh group.
I'm just simply asking whether these could be risks in the non-mesh group.
A. Yeah, but with the caveat, you have a totally different population.
Q. Well, we'll -- I will stipulate for all of these questions, they are two different populations.

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I'm not asking you to compare the two populations.
A. Right.
I will answer, yes, they will have that risk, but with the caveat that we're talking totally different, apples and oranges.
Q. Understood.
And so you would agree that chronic pain is a risk of non-mesh SUI surgery?
A. It can be, yes, sir.
Q. Vaginal scarring is a risk of non-mesh SUI surgery?
A. I don't know about vaginal scarring. I'll leave that one as I don't know.
Q. Infection is a potential risk of a non-mesh SUI surgery?
A. Infection can be a risk of almost any surgery.
Q. And urinary problems, including urinary frequency, retention, obstruction, urge incontinence, and voiding dysfunction could be potential risks of a non-mesh SUI surgery; correct?
A. Yes. And you're not talking in time frames either, because you can have infection acute in terms of postop, but would you see chronic infection without a mesh? Probably not.

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And so, you know, you're not qualifying who the sick people are, and then we're also not putting in the time frame, because infection is more postop for a non-surgical mesh, whereas it's chronic in women who have a surgical mesh, that their mesh gets infected, so it's different.
Q. Understand.
Is organ or nerve damage a risk of non-mesh SUI surgery?
MR. JONES: Objection.
THE WITNESS: It can be the same caveat. And then you're talking about the transobturator pap is usually the one who would see the mesh with the nerve injury.
BY MR. GAGE:
Q. Is bleeding a risk of non-mesh SUI surgery?
A. Bleeding is a risk of any surgery acutely.
Q. Are wound complications a risk of non-mesh SUI surgery?
A. Acutely, yes, sir.
Q. Not chronically?
A. Not typically chronically, no. You tend to be acute postop, period.
Q. You used the word "typically."
Can wound complications -- can chronic wound

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complications ever occur with a non-mesh SUI surgery?
A. They can occur, yes.
Q. Can inflammation occur with a non-mesh SUI surgery?
A. Inflammation? What kind of -- I mean, are you talking about inflammation in terms of infection or red, or what are you talking about?
Q. Inflammation of the human tissue.
A. It's kind of a generic term.
Q. If you can't answer the question, then you can't answer it.
A. Yeah, it can occur, but it's just too nonspecific.
Q. Can fistula formulation occur with a non-mesh SUI surgery?
A. It can occur.
Q. Can neuromuscular problems in the groin, thigh, leg, pelvis, or abdominal area occur in a non-mesh SUI surgery?
A. Yes.
Q. And is it sometimes necessary for one or more surgeries to be conducted in order to treat an adverse event arising out of a non-mesh SUI surgery?
A. It can be.

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Q. Can a foreign body response be a risk of a non-mesh SUI surgery if a foreign body is used?
A. Well, did they -- did they use a foreign body? I mean, if they used a foreign body, yes.
Q. And we talked about this in the Prolift+M deposition. I'm not sure it's absolutely necessary that I re-ask it, but I don't want you to later say, well, I was talking only about Prolift+M, so I'll ask this question.
Well, no, I won't. I'll strike that.
Doctor, are you aware that some doctors did not read the TVT-Secur IFU before implanting the device?
A. You know, I think we talked about that today. Yeah, some doctors may not. They may have relied on the sales rep, the training, the course, other things besides the IFU.
Q. Is it acceptable medical practice for a pelvic floor surgeon to implant a Secur device without first reading the IFU?
A. Well, they obviously have training in it, and so where are they getting their training? The IFU oftentimes drops into the surgical field, and you're not going to sit there in the OR reading it. So it depends. I mean, obviously they've had some

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training.
Q. When and how often should surgeons read the IFU?
A. Usually the sales reps are the ones who bring it to them and say, "Here. Read this," and they go through the different features of the product, and they go through telling them what they need to know. So an IFU is often interacted with the sales force.
Q. How often should they read it? Should -- strike that.
How often should a surgeon read the TVT-Secur IFU?
MR. AYLSTOCK: Objection. Form. Asked and answered.
THE WITNESS: Well, the sales rep usually tells them if there's something new in it or if -- so they're interactive with the sales reps at the same time, so --
BY MR. GAGE:
Q. Let me change the question.
A. Yeah.
Q. I may have confused you.
For purpose of this question, assume that the IFU does not change, that it's the same IFU.

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Do you have an opinion as to how often a surgeon should read that IFU?
A. No.
Q. Is there any regulatory standard that requires them to read the IFU?
A. No. That's -- that's medical practice. That's not FDA.
Q. Have you conducted any study or survey of pelvic floor surgeons to determine whether they read the Secur IFU?
A. No.
Q. Have you conducted any study or survey of pelvic floor surgeons to determine what risks they understood as a result of --
MR. AYLSTOCK: You're now asking the exact question precisely that was asked in the prior deposition.
MR. GAGE: Oh, wow.
MR. AYLSTOCK: You're almost going off the same --
MR. GAGE: What page are you on?
MR. JONES: I mean, it's fair to say that the IFU brochure was covered at length in --
MR. AYLSTOCK: Page 121, line 12, "Do you have any study or survey of doctors in what

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risks from the TVT-Secur device they appreciate from the IFU?"
BY MR. GAGE:
Q. All right. Then I'll ask it like this: Doctor, since February of 2015, have you conducted any study or survey of pelvic floor surgeons to determine whether they ever read the Secur IFU?
A. No.
Q. Since February of 2015, have you conducted any study or survey of pelvic floor surgeons to determine what risks they understood as a result of reading the Secur IFU?
A. No.
Q. Have you conducted -- since -- I'm sorry. Strike that.
Since February 2015, have you conducted any study or survey of pelvic floor surgeons who implanted Secur to determine what risks of the device they understood as a result of their medical school education?
A. No.
Q. Since February 2015, have you conducted any study or survey of pelvic floor surgeons who implanted Secur to determine what risks the device they understood as a result of their surgical

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training?
A. No.
Q. Since February 2015, have you conducted any study or survey of pelvic floor surgeons who implanted Secur to determine what risks of the device they understood as a result of reading relevant medical literature?
A. No.
Q. Should pelvic floor surgeons implanting Secur read the medical literature about the device?
A. Yeah, I don't have an opinion about that. I mean, they're responsible for their practice.
Q. Could doctors have learned of the risks of TVT-Secur from reading medical literature?
MR. JONES: Objection.
THE WITNESS: More likely they would have been able to learn it from Ethicon than in the literature.
BY MR. GAGE:
Q. But could they learn of risks from reading the TVT-Secur literature?
MR. JONES: Objection.
THE WITNESS: They could if there was such literature out there.
///

BY MR. GAGE:
Q. With regard to the literature that you reviewed in connection with your TVT-Secur report in the MDL, is it fair to say that the literature you reviewed would be included either as a citation in your report itself or in your reliance list or in this document marked as Exhibit 6 or otherwise marked as one of the exhibits at this deposition?
A. I believe so.
MR. JONES: Objection.
If you want me to explain, I will.
MR. GAGE: Yes. Give me -- explain your objection.
MR. JONES: And this goes back to earlier today.
You're going to be asking about literature, and that was why I got hung up. You kept using the word "documents," and I kept bugging you and being annoying about internal documents. I'm sure that was very annoying.
MR. GAGE: Actually, it wasn't. You've been -- you're not bothering me.
MR. JONES: The literature -- you know, lots of times Ethicon -- you know, this literature will be listed under ETH.MESH number, you know, and

there's clinical export reports. There's FDA literature. There's Cochrane.
And so what I don't want to get in a situation of is someone just going through the reliance list and saying, gotcha. This one isn't on there. And then, well, it's in the clinical expert report that is in the box that you had for, you know, a year.
Or, gotcha. It's not on your reliance list. I got -- I handed you in the depo. You made a reliance list under literatures, all the literature reviewed. But, oh, wait. It's listed in the -- you know, as an ETH.MESH Bates number because there was an e-mail sent with three articles attached.
That's what -- to me, the objection is so I have an opportunity to explain it at a later point if this becomes an issue that, oh, here's the same article. Why isn't it in the literature tab on the reliance list, but it was in the box, or it was in the report or it was in the clinical expert report or it was part of the Cochrane or it's part of the literature review that she talked about.
So that's my objection.
MR. GAGE: Got it.

MR. AYLSTOCK: And just to be clear, again, there's extensive questioning on her reliance list and the scientific literature in the prior deposition. And in particular, the Cochrane report and others, so I think we're really --
MR. GAGE: I'm limiting my question to the literature she's reviewed for her TVT-Secur MDL report.
MR. JONES: I think she's already said it's essentially the same.
MR. GAGE: All right. So let me ask that question. I don't think I've asked that question.
BY MR. GAGE:
Q. Since your disclosure and deposition in the TVT-Secur case in the Garcia matter, have you reviewed any additional or new medical literature pertinent to TVT-Secur?
A. No.
Q. So whatever TVT-Secur literature may have come out since February of 2015, you would not have reviewed it. Is that correct?
A. Yes.
Q. Okay. Since February 2015, have you conducted any study or survey of pelvic floor

surgeons who implanted Secur to determine what risks of the device they understood as a result of their experience implanting other mesh devices?
A. No.
Q. Since February 2015, have you conducted any study or survey of pelvic floor surgeons who implanted Secur to determine what risks they understood as a result of participating in any training on Secur?
A. No.
Q. Since February 2015, have you conducted any study or survey of pelvic floor surgeons who implanted Secur to determine what risks they understood as a result of participating in Ethicon-sponsored training on Secur?
A. No.
MR. JONES: Form.
MR. AYLSTOCK: Let me just say, William, if we're going to preface every question that was already asked in the prior deposition with, "Since the prior deposition," then I'm going to insist on taking every one of your experts again because their depositions were done months or years ago. And I'll ask every question starting with, "Since," and that will cure the problem.

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So, I mean, really none of the questions you're asking are on the e-mail where you specifically said, "Here's some new things I would like to ask about." They're just fishing, so it's really getting far afield.

MR. GAGE: I understand your objection.

And my concern is that I got a 115-page report, I had a five-page disclosure, and then there's been a year -- there's been a year in-between. And I don't know what you guys have asked her to do or examine or look at or what she's done in that intervening year.

MR. AYLSTOCK: But all of her opinions are in her report. You know, Judge Goodwin is going to insist that her report is the end all, be all of what her testimony is going to be.

So, again, it's not in her report that she did any sort of survey. We're just in my view replowing old ground, and that's not what I thought we were going to be doing.

But go ahead. I'm not telling her not to answer or anything. I'm just making my record.

MR. GAGE: I'm actually finished with that line of questioning.

MR. AYLSTOCK: I'm glad I made the

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record when I did.

MR. JONES: Yeah. It worked.

MR. AYLSTOCK: Either it worked or I was one question too late.

MR. GAGE: All right. Now, these are questions that I have to ask the witness about since February of 2015 because new things have occurred, including things that have occurred after her report was written.

MR. AYLSTOCK: Okay.

MR. GAGE: And I have to ask -- I'm not trying to be duplicative.

MR. AYLSTOCK: I'm not trying to be obstructive.

MR. GAGE: Truly, I just -- I have to make sure that I don't get blindsided with this.

BY MR. GAGE:

Q. And so here's the question, for example. I know that there have been -- since the time of your MDL expert report was written, you've looked at new documents from FDA that were obtained by -- through some Freedom of Information request; correct?

A. Um-hmm, yes.

Q. Had you looked at those at the time of the Garcia deposition?

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A. The ones that I gave you today?

Q. Yes.

A. No.

Q. Okay. There have also been some additional public pronouncements by FDA with regard to surgical mesh; correct?

A. Yes.

Q. Okay. So I'm not trying to be duplicative of prior questions, but new materials have come to light --

A. Right.

Q. -- and I feel compelled to ask you these questions.

Has anything in these new materials that you've examined led you to believe that FDA ever recommended any labeling changes for Secur after it was cleared?

A. No.

Q. Has FDA ever determined that the Secur labeling was false or misleading?

MR. JONES: Objection.

You're tying this to specifically those new documents, or are you asking generally?

MR. GAGE: Yeah, to the new documents. I mean, I haven't looked at --

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MR. JONES: That's not how your question was phrased. That's my objection.

MR. GAGE: Well, I prefaced the --

MR. JONES: So every question from hereon after is limited to those two new documents?

MR. GAGE: I'll tell you what. Why don't we do this. With regard to the -- I'm going to ask you a series of questions with regard to the new information that you have been provided since the time of your Garcia deposition, and then when I finish that sequence of questions, I'll announce it so that that condition no longer applies to that question, or do you want me to just put it in the question?

MR. JONES: Yeah, I want it in the question.

MR. GAGE: Okay.

BY MR. GAGE:

Q. Have you seen anything since your deposition in the Garcia case in February 2015 that would lead you to believe that the FDA determined that the Secur labeling was false or misleading?

A. Well, in terms of those are regulatory terms, and so are you saying that I've seen a document where the FDA came out and said that?

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Cause then there's internally discussions, but there's not a document where they said that the label is false and misleading, other than, how did this product get on the market, and some of the issues with it and so -- but there's no specific pronouncement that they said that.

Q. All right. Let me follow up.

You just said, other than how did this document -- how did this device get on the market?

A. Well, yes. When you look at the document that I gave you in terms of the FDA's discussion internally about mesh in general, there's -- there's --

Q. Do you have that document?

MR. JONES: It's in the box. Right corner, I think.

BY MR. GAGE:

Q. Oh, this one?

A. Yeah.

Q. Let's make sure we're talking about the right document.

Are we talking about the collection of documents received --

A. Right.

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Q. -- from the public records request?

A. Right.

Q. All right. So that's Parisian TVT-Secur Deposition Exhibit No. 7?

A. Right.

So there's discussion in there how the FDA -- how did something get approved for transvaginal insertion. And so FDA's going back and forth trying to figure out, how did that happen.

And then they talk about, they're looking for unsubstantiated claims. We don't know what happened with that. So, I mean, they're actually looking at stuff like that, and I don't know what the conclusions were.

But in terms of the advisory group here, that they were looking at the labeling. They were looking at how products got on the market, like the Prolift. They knew that the Prolift had been on without any clearance, so there's actually internal discussion by the FDA as to what they knew. But they didn't say false and misleading.

Q. Is there anything in the -- in Exhibit 7 that pertains specifically to TVT-Secur?

A. I believe they talk about TVT-Secur in there. They talk about Prolift. They talk about

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TVT-Secur. And then the other guidance document or the other reclassification, they talk about TVT-Secur. So there are places where they mention it and Prolift.

I mean, that focus of that package is on Ethicon. They weren't looking at any other manufacturer. They were looking at Prolift and TVT-Secur.

Q. Do you know why that was the case?

A. No. FDA chose to go -- they apparently had gotten some reports to Office of Compliance, and they were looking at -- I believe they were looking originally at hernia and got -- Ethicon's a big group in terms of hernia repair, and then they segued into transvaginal mesh.

Q. Did -- if having now reviewed the documents in Exhibit 7 now that your MDL report is -- well, you reviewed the documents in Exhibit 7 after your MDL report came out; correct?

A. Yes, sir.

Q. Do you intend to write a supplement to address these documents?

A. No, sir.

Q. Can you tell me how these documents support or refute your opinions?

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A. They complete the picture of what I thought was going on, that there actually had been decisions -- I've been on committees like this where you have a problem, and then you're trying to figure out how to deal with it from the FDA's point of view.

And so it just kind of tops off what I thought was occurring. I think I had seen in other documents that the FDA had created a group to look at some of these things.

So it just -- it's just -- it makes it much more complete. Why did the FDA come out with a public health notification? That really discusses why.

Q. What is the date?

A. 2007, 2008, so it's before the public health notification in October 2008.

Q. Is it before the -- when was the TVT-Secur 510(k) cleared?

A. Oh, gosh. 2000- -- wasn't that around 2007? So we're talking about the same time frame.

Q. Do you know any of the individuals on the surgical mesh action team?

A. Some of them I do.

Q. All right. So you're not intending on

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writing a supplement based on these documents?
A. I haven't been asked to do that. So let's see. I think it was around -- TVT-Secur --
Q. So --
A. It was November 30, 2005, so this actually was occurring after TVT-Secur had been on the market.
Q. All right. So is there anything in that Exhibit No. --
MR. JONES: Seven -- six -- seven.
BY MR. GAGE:
Q. -- where FDA makes any conclusion as to whether the TVT-Secur labeling was false or misleading?
A. Well, basically, when they're talking about the MDRs and the reports they're receiving, they know that the labels don't have that. And so that technically would be, you know, false -- false and misleading in terms of the FDA to try to get the information out to the public.
And that's one of the reasons they're trying to do a Section 522 postmarketing study, so they could update the information for the user.
So basically you would pursue something like this or you think that the literature for this --

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they look at GYNEMESH, TVT, that the labeling is not reflecting the information that they're seeing in their medical device reports.
Q. Let me change the question. Does that document you're holding in your hand hold a determination or final conclusion by FDA that the TVT-Secur labeling was false or misleading or inadequate?
A. They're looking at all the transvaginal mesh, not specifically for the TVT-Secur, because you're asking me specifically about that?
Q. That's correct.
A. No. They were looking at the entire group of products as not having adequate information for the -- for the physician and the patient.
Q. Is there anything in that document that constitutes a final determination by FDA that the TVT-Secur device was misbranded or adulterated?
A. No. You won't see that in here.
Q. Is there any conclusion or determination by the FDA that Ethicon failed to provide FDA with relevant safety information about TVT-Secur?
A. No.
Q. Is there anything in that document that is a conclusion or finding by FDA that the TVT-Secur was

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illegally marketed?
A. Illegally marketed, no, but there is a conclusion that the FDA is going to call for 522 studies. 522 studies by definition would be that there's not enough postmarketing information, and that would include TVT-S, and that would include all the other TVT products.
So does that answer your question?
Q. Is that tantamount to a declaration that TVT-Secur was illegally marketed?
A. I didn't say it was illegally marketed. It was marketed under a 510(k). What was illegal about it was it wasn't performing the way it was cleared, so it was a prohibited act because it wasn't fulfilling what was said in the 510(k).
Q. And I'm just -- my opinions are limited to just that particular exhibit --
A. Right.
Q. -- because that's something that you got after you wrote your FDA -- I'm sorry -- after you wrote your TVT-Secur opinion.
A. Yes.
Q. And I just want to make sure that nothing in that document in your opinion constitutes a finding or declaration by FDA that TVT-Secur was illegally

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marketed.
A. No. I wouldn't expect -- I mean, it's not the FDA's job under 510(k). It would be the company's to say that the product is not marketed because it's not performing the way it's supposed to.
I mean, the FDA's big thing is something needs to be done. They need post-market surveillance. They need some information out there. They need post-market studies.
So the FDA is trying to correct the issue for the public. Not necessarily to -- they're not focusing on just TVT-S.
Q. Dr. Parisian, several times -- well, a number of times in your TVT-Secur MDL report, you indicate that Ethicon withheld certain information from FDA.
A. I think what I said was they didn't completely disclose the issues that were occurring so that FDA could consider what was going on and ask for new additional information.
Q. All right. So I've got phrases throughout your report, and I'm just quoting one. I think it's Paragraph 228, where you say, "Ethicon did not fully and accurately disclose certain information."

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A. Yeah. That's like what I just said.
Q. And then in another place in your MDL report, you opine that, quote, Ethicon withheld key information that was necessary for FDA to determine whether clearance of the 510(k) should occur?
A. Yes. That means it was not in the application, and it was something they would have had.
Q. Now, Dr. Parisian, it would -- it would be extraordinarily time-consuming for us to go through the report and identify each and every place where you have a phrase that is either identical or similar, i.e., Ethicon did not fully and accurately disclose, Ethicon withheld, et cetera.
I think it's fair to say -- and I think you agree with me -- that phrases -- those words or phrases similar to those words appear frequently in your report. Is that fair?
A. Well, if you go to the Paragraph 228, I specifically say what I'm talking about in terms -- I mean, I don't just say that lightly. I go on and I talk about that the 510(k) didn't really tell the difference between a TVT and a TVT-O, and there was no way somebody could under- -- you know, determine that the TVT-S was totally different.

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So, I mean, I go on, and then I talk about the French data, and so I'm usually giving specific examples. I don't just say -- I'm telling you what I think they withheld.
Q. Right. And I wasn't suggesting that you didn't do that.
I'm just asking you that -- to agree, if you want to, that there are a number of places in your MDL report where the sentence contains phrases like "Ethicon did not fully and accurately disclose certain pieces of information" --
A. Right.
Q. -- or "Ethicon withheld certain pieces of information."
Would you agree with that?
A. Yes, and then I give the information, why is it important in terms of the reviewer, because the whole thing is to trigger if there's new issues of safety and effectiveness.
Q. Right.
A. And so if they don't have that information, then they can't ask for additional testing.
Q. All right. My question to you is, with regard to anything in your MDL report, is it your opinion that Ethicon at any place intentionally

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withheld information from the FDA?
A. I don't know why they did it. I mean, it's just a fact that certain information wasn't put in there that I think should be important information. They could be the stupidest people in the world. That might have been it. They could -- so who knows why they did it. It's just a fact that that information wasn't there, and if I was writing a 510(k), I would have included it.
Q. Could it have been a difference of -- a good faith difference of opinion between you and the Ethicon employees?
A. I don't know. I mean, let the courts decide.
It's like that one truthful and accurate statement, I don't know why they always wrote it a different way. Somebody made them write it a different way. Someone told them to do it. Who knows? I don't know why they did it.
But when you go through the 510(k), those are the things that you see that you think somebody should have told the FDA about. If I was a reviewer, I would have wanted to know.
Q. So I'm trying to understand -- like when you use phrases like "Ethicon withheld key information,"

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I'm trying to understand, do you have evidence of intent to withhold?
A. No. It's just not in the 510(k).
Q. Okay. And that would hold true for not just Paragraph 228 but for the entirety of your report where you have an opinion that Ethicon did not fully and accurately disclose certain information or that Ethicon withheld information, in all of those instances or in none of those instances, is it correct to say that you have evidence of actual intent?
MR. AYLSTOCK: Object to the form of the question.
THE WITNESS: If indeed the company has a statement or e-mail or something that says why they did something, then I would give that.
But if I don't have something to tell me what their intent was, then I'm just going to leave it general. Let the court decide.
But if I -- there are times when the company -- company says, we're doing this. This is what our strategy is going to be. Well, that would be intent, that I can say, but if I don't have information to support it, I usually just leave it, it's not there.

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BY MR. GAGE:
Q. Okay. And I think with regard to the internal e-mails where they may have declared their intent, did you find any internal e-mails or other company documents where, in your opinion, Ethicon consciously attempted to defraud the FDA?
MR. JONES: Objection.
THE WITNESS: That's not something I would talk about. I mean, because, I mean, there are things where the company has made a decision what they're going to do in terms of marketing, what they want in terms of marketing share.
That would be -- you know, their intent so to sell products, but defraud the FDA, that sounds like a legal conclusion, and I don't make legal conclusions.
BY MR. GAGE:
Q. Well, let me ask you this: Did you find any e-mails that, in your opinion, state, "We, Ethicon, are going to not share this with the FDA so that they will not know what we know"?
MR. JONES: Objection.
THE WITNESS: I don't recall. I'm not going to say no. I'm not -- I just -- I don't recall at this moment in time because there are

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things where they talk about the FDA and their strategy with the FDA. If I saw such a document, it would be in my report.
MR. AYLSTOCK: Can we take a quick break whenever you get a chance?
(Recess taken.)
BY MR. GAGE:
Q. All right. Dr. Parisian, we're back on the record.
Have you endeavored to undertake an analysis of any of the TVT-Secur MAUDE reports?
A. No.
Q. Have you undertaken any analysis of the TVT-Secur issue reports at Ethicon?
A. The issue reports in terms of the manufacturing.
Q. Let me withdraw that question --
A. Okay.
Q. -- and let me get straight to it.
I didn't see the report -- I didn't see this opinion in your MDL report, but I just want to make sure, as with Dr. Pence, it's not somewhere lurking out there for me.
Do you intend for TVT-Secur to offer any opinion that Ethicon was in possession of certain

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issue reports or product complaint reports that it should have reported to FDA but didn't?
A. I haven't done that review, so I don't intend to do it. Someone may ask me to do it, but I haven't done it.
Q. Okay. So you don't have, for example, a list of either specific complaints or specific instances that you saw in the Ethicon documents and then you went to the MAUDE database, and you didn't find an instance that you felt should have been reported, and you would come to a jury and say, "Ladies and gentlemen of the jury, here are whatever the number of internal complaints or issue reports that they should have reported to the FDA. I went to the MAUDE database, I checked it, and they didn't do that"?
A. No. I would look at the company documents looking for what they're receiving as reports, but I haven't done that in terms of the MDRs.
Q. Okay. In your report, you indicate that -- and I'm talking about your MDL report -- that the FDA's 510(k) process -- and I'm using your words -- the FDA's 510(k) process admittedly has weaknesses, including FDA's required reliance of the truthfulness and accuracy of the information in the

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sponsor's premarketing application.
A. Yes.
Q. Do you remember that?
A. Yes.
Q. Because of the way it's worded, i.e., the process admittedly has weaknesses including --
A. Um-hmm.
Q. -- and you point out the FDA's required reliance of the truthfulness and accuracy portion, are there other weaknesses, in your opinion, of the 510(k) process?
A. One is you have a reliance on pre-amendment biomaterials. Our country tends to only get things approved or cleared that have been on the market since pre-'76. So inadvertently the 510(k) is locked. This is the pre-1976 mentality for materials where the rest of the world may use other materials, and so I think that's one of the weaknesses of the 510(k) process.
Also, the idea that everything is grandfathered from the pre-amendment devices in the '90s, that -- that's got some flaws in it.
Q. Let me interrupt you and be more precise with my question.
In your opinion, does the FDA 510(k) process

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have any weaknesses that would be pertinent to TVT-Secur?
A. Yeah. Because in one of the things, the FDA 510(k) process is required to use the least burdensome methods, and so manufacturers can cite something else being cleared, like the Dura Patch, and that is a cleared device in a neurological indication.
And so because it is cleared, Johnson & Johnson can then use it in a new intended use, and they can -- they can just cite the 510(k). They don't necessarily need to go out and provide the FDA with data.
FDA is bound to just the least burdensome, so the FDA can't really ask for more testing.
Even when -- what is it? -- TVT-Secur, when Dr. Herrera asked for a clinical study for a 12-months data, they came in with a 510(k) for the Gynecare Tape, and FDA then can't ask because they had already cleared a device that was a mini tape type thing. So there's limitation to what the FDA can do based on the 510(k) process.
And then also now we have the MDUFA user fees, which they have only 90 days to get a 510(k) done, which is actually a fairly quick turnaround

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time.
And so there's -- there's things about the FDA process to try to get new products in the market for the public that make it difficult for the FDA reviewer to get more data.
They have -- it's easier to clear stuff than to not clear it.
Q. Are there any -- are there any additional weaknesses of the 510(k) process that you perceive that are pertinent to TVT-Secur?
A. Well, in this particular case, the issue is that the FDA was clearing transvaginal mesh as basically surgical mesh, and they weren't asking for any clinical data. They were just basically using a checklist. You know, what is the porosity? What is --
And that was basically what the clearance was, and so that was based on the 510(k) process for general surgical mesh based on mechanics, mechanical properties of mesh.
So in some way that -- that actually hurt the TVT products, TVT-S, because the FDA was using basically a checklist. Oh, here's what the mechanical properties are.
And in this particular case with the TVT-S,

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the FDA was told it's less invasive because there's only one incision, but that doesn't mean it's less invasive. That means it can be even more difficult to put in, but the FDA accepted that Ethicon said it was less invasive, and there really wasn't any data to support that.
Q. All right. So I want to stay focused on the process, not so much --
A. TVT-S?
Q. Your statement in the report was the 510(k) process has weaknesses --
A. Right.
Q. -- and you moved on to a discussion of --
A. TVT-S?
Q. Well, let me finish.
I want -- I would like for you to identify, and maybe you've already done it fully, but I would like for you to identify any weaknesses in the 510(k) process that are pertinent to the TVT-Secur.
A. I was trying to do that.
Q. Well, let me make a distinction.
When you said that FDA accepted Ethicon's statement that TVT-Secur was less invasive, I don't view that as part of the -- I'm talking about the organizational structure of the 510(k) process --

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A. The biomaterial is a big one.
Q. -- that would have applied to TVT-Secur. I'm not so much asking about what could FDA have done differently within the existing structure.
A. Okay. If we just talk about the process, the biomaterials, in that you have polypropylene implanted in women back before 1976, so it's a pre-amendment product that nobody has really looked at, has a long history of use in surgical mesh, but because it was a pre-amendment product, nobody's really looked at it, so that's part of the process.
So we basically tied our biomaterials in the United States to pre-1976 because it's much easier for a manufacturer to use a pre-1976 material than to go and develop a new material.
And so inadvertently the 510(k) process has held us to older technology or biomaterials, so that's one of the big things.
The other one is the process, the least burdensome. Since 1997 -- yeah, 1997, they had -- the FDA reviewers were required to use the least burdensome method for industry to get clearance.
And so, therefore, it limits what the FDA can request in terms of, they can't request just -- you know, if you have not requested it from somebody

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else, clinical data, you can't request it all of a sudden from somebody else without support, so the at least burdensome is another one in there.

The truthful and accuracy statement we have there because the FDA is to assume that there's no material fact not being provided because they sign a certificate.

Well, you know, that isn't always the case. The manufacturers haven't been providing the information to the FDA. So those are three big ones, the least burdensome, biomaterials, and what's the third one?

Q. The truthful and accurate.

A. The truthful and accurate. And then MDUFA, people have also looked at MDUFA in terms of having to have something get done within 90 days. Otherwise, the reviewers are held responsible if they take longer. You could only ask for two additional information rounds.

So those are things that put a lot of pressure on the reviewer to get something done very quickly.

Q. Are you critical of congress for those features of the process, or are you critical of the FDA for those features of the process?

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MR. JONES: Objection.

THE WITNESS: Well, it would be both, because some of those features were developed by the FDA. The FDA developed the 510(k) process. Congress actually thought the PMA would be used more frequently. FDA really got into the 510(k) process, so the 510(k) process has been developed internally more or less.

The least burdensome actually came from congress in terms of FDAMA in 1997, so that was congress. The Medical Device User Fee Act was also congress. So it's both of them.

BY MR. GAGE:

Q. All right. And would it -- is it fair to say that you disagree with either congress or the FDA on those issues that you have identified?

A. I don't disagree.

I mean, I just know from, having worked there, that these are constraints. And when you worked there, these are constraints that you had. You just weren't allowed to ask for anything.

So am I complaining about them or what? I'm just saying, these are the constraints that a reviewer has to work with.

Q. All right. And with regard to TVT-Secur, I

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understand it's your opinion that it was not a safe and effective device from day one, and it should never have been cleared.

Is that a fair statement?

A. Based on the information that they had, I don't think they had sufficient information to show that it would be substantially equivalent to the Gynecare tape. That was what it was actually cleared against. It wasn't actually cleared against TVT-O or TVT.

I think the use of the CODMAN Dura Patch was kind of iffy. That was not a good design thing. And you could do it, but I don't think it was actually tested to make sure that it would be -- hold in place.

Q. If the 510(k) process for TVT-Secur had been different, do you believe the FDA would have reached a different decision with regard to the clearance of TVT-Secur?

A. No. I mean, I'm going to say that the TVT-Secur is cleared. It was cleared. And so what does that mean if Ethicon gets a clearance? It means they have to have the device that actually performs the way they described it in their 510(k), and that's really where it all falls down.

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If Ethicon did get clearance; therefore, they needed to market the product that behaved the same way that they said TVT-Secur would work. When it doesn't work, then you're not marketing the device that was cleared under the 510(k).

And so it's -- that's where your post-market surveillance comes in. Once you realize it's not working that way, you shouldn't be selling it.

Q. Maybe I misunderstood, but I thought that your opinions with regard to TVT-Secur are impacted -- strike that.

I understood that it is your opinion that certain features of the 510(k) process allowed the device like TVT-Secur to get clearance when it should not get clearance under an appropriately rigorous clearance process.

Is that your opinion?

A. I look at it as the risks that I'm seeing and saying were foreseeable to Ethicon as the expert in this design of this product. They should have seen this.

It has nothing to do with the FDA. It's more with Ethicon in terms of the CODMAN and the use of these products.

Q. I know, but I'm trying to understand why you

put in your expert report that the FDA's 510(k) process has weaknesses.
A. It does.
Q. Have we discussed those weaknesses?
A. Right.
Just because you get 510(k) clearance doesn't mean your device is going to work, and so there are weaknesses. It's not a PMA approval process or anything. It's -- it's -- but it has limitations.
And the FDA can't ask for more information unless they have certain key things to let them do it. Yes, it's a weak -- it's got system problems, but the issue is you can't market something that doesn't behave the way it's cleared.
Q. Right.
A. So, you know, it's -- yes, indeed the FDA cleared it, but the FDA cleared it, and so then -- the FDA clears devices that there is no device even made. You're describing in your 510(k) what you're going to sell.
Q. But as I understand it, the FDA -- it is your opinion that the FDA cleared TVT-Secur under a process that is flawed?
A. Yeah.

It has limitations to it, and so if -- somebody thinks there's a loss of testing, and there's not. It's a limited system. There's certain restrictions on the FDA.
FDA can only trigger and ask for certain things if other things occur, so it's -- it's got all kinds of pitfalls in it, but the bottom line is you can't sell the product if it doesn't behave the way you're cleared.
Q. And is it my understanding that in your opinion there are only two organizational bodies that could apply fixes or remedies to that 510(k) process, and that is either congress or the FDA?
MR. JONES: Objection.
THE WITNESS: Well, if you're talking about changing the laws, the congress is the one who gives all the authority and the requirements. The FDA tries to interpret the laws to fit what congress says, but it is a flawed system.
It's not what -- people think that it's perfect. But the bottom line is, you can't sell. It's a prohibited act, not for the FDA but for the manufacturer, to sell a product that doesn't behave the way it's cleared.
///

BY MR. GAGE:
Q. Okay. And have we identified the flaws in the process that you believe impacted the clearance decision for TVT-Secur?
A. Well, and also I didn't get to say about the --
Q. Could you answer that?
A. Almost, almost.
Q. Have we discussed them?
A. Almost, except for one other thing.
Q. Okay.
A. And that would be the use of the Dura Patch. That -- that really was able to be bridged because it was already a cleared device.
So there was minimal requirement for the company to provide anything to the FDA on that, and so it's the bridging system, that if something is cleared, you can bridge it for a new intended use, and, yet, you may not have done clinical studies to make sure that it's actually -- they did a sheep study, but the sheep study is pretty inadequate, the way it's designed.
Q. All right. And, Dr. Parisian, on -- in paragraph 80, page 36 of your report, you have a sentence that says, "To clear the 510(k) for

Ethicon, FDA's ODE reviewer requested no information on the PROLENE Surgical Mesh Sling, but short-term clinical or animal data from Ethicon to support the feasibility that Ethicon's proposed TVT tape procedure could be learned and used by surgeons to implant a PROLENE sling with Ethicon's accessories and instructions."
Do you see that?
A. Yes, sir. That's talking about TVT. That was the history of TVT getting cleared.
Q. Okay.
A. Yeah. This was --
Q. I was trying to understand the import of this sentence --
A. Oh.
Q. -- at two levels.
And my first question is, are you -- are you critical here of the ODE reviewer for not requesting additional information?
A. No.
And -- and the thing here is that ProtoGen was out on the market, and they had to give information -- ProtoGen was actually selling well at the time TVT was cleared.
Q. Can you tell me, though, specifically what

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you mean when you said, "To clear the 510(k) for Ethicon, FDA's ODE reviewer requested no information on the PROLENE Surgical Mesh Sling, but short-term clinical or animal data from Ethicon"? The sentence sounds like the reviewer could have requested other information but didn't.

And that's what I'm trying to ask. Is that what you're suggesting?

A. Well, I'm saying -- I'm saying requested would mean he didn't demand it, he didn't require it. He could request it.

And so the ODE reviewer could have requested, but since PROLENE is a cleared product, PROLENE mesh, it would be unlikely that he could force Ethicon to provide him stuff about the PROLENE mesh sling, and so he could ask for something that was new, which was the animal data about implanting the tape sling would meet equipment. So there's limitations as to what the FDA could request, and I'm not saying require. I'm saying request.

Q. So is -- what I'm trying to understand is what you're saying is he had the power to request it, but he didn't?

A. No. He didn't have the power to request it because Ethicon could have told him to go pound

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sand. I mean, the thing is, they didn't ask for it from ProtoGen, so he can't -- he can't require it. He can request it.

Q. I understand. I have to --

MR. GAGE: I got to move to strike the answer.

BY MR. GAGE:

Q. My question is very specific.

A. Uh-huh.

Q. Are you critical of the ODE reviewer for having the ability to request additional information and not actually requesting it? That's my simple question.

A. No, I'm not critical of the FDA reviewer, because the FDA reviewer could request it nicely and say, "Could you please give it to me?" And that's what I'm saying. Not that he could require it. He couldn't require it.

Q. Well, why did you point out that he requested no information other than short-term clinical or animal data? The sentence implies he could have requested more.

A. He could have requested it, but Ethicon wouldn't have to give it to him.

Q. I understand. But he could have requested

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it?

A. He could have requested, but he didn't that I saw, and what he requested is what he could get.

Q. And we're not to read that sentence as you're being critical of the ODE reviewer for not making the request?

A. No.

Q. Why did you write it, then?

A. It's because it's describing the process, that in terms of PROLENE, the FDA knows that it's already approved as a mesh, so there's very limited information you can ask about PROLENE mesh because it's been marked since the pre-amendment time.

So he could request it, but he didn't, and he could request animal data, which is what he did request. And so he did get some animal data about putting the kit, because that's a new safety issue. PROLENE mesh is not a new safety issue, so it's describing limitations to what FDA can request.

Q. And this would go back to one of the weaknesses in the 510(k) system --

A. That's right.

Q. -- that you identified earlier?

A. That's right. That was with the biomaterials and being able to reference, you know,

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other devices that are cleared.

PROLENE mesh has been cleared, so there's very limited information that an FDA can request.

Q. So would it be correct to say that the weaknesses in the 510(k) process affected the decision to clear TVT-Secur, not just in the context of the 510(k) for TVT-Secur, but also in the 510(k) process for all of the predicate --

A. That's right.

Q. -- devices for TVT-Secur?

A. That's right.

Q. So the weaknesses of the 510(k) system with regard to ProtoGen and TVT and TVT-O all fed into additional weaknesses that manifested during the review of the TVT-Secur 510(k), all of which to some degree led to, in Dr. Parisian's opinion, a flawed decision to clear TVT-Secur?

A. It wasn't the FDA's flawed decision. It was just the process allows the product to get on the market that may not be safe and effective.

Because when you look at a TVT-Secur, it wasn't cleared on TVT or TVT-O. It was cleared because they found a 510(k) for the Gyne Ideas tape, and because they found a cleared 510(k) for its small tape, FDA couldn't ask for clinical data.

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Dr. Herrera wanted 12 months clinical data, and it totally negated what FDA could ask for when the company found a predicate.

MR. AYLSTOCK: And you're down to about eight minutes, just so you know.

MR. GAGE: I'm down to about eight minutes? Okay. Thank you.

BY MR. GAGE:

Q. Have you looked at any expert report by Dr. Thomas Mule?

A. No.

Q. Do you know who Dr. Thomas Mule is?

A. No.

Q. Okay. Dr. Parisian, with regard to this deposition Exhibit 8, which was one of the documents you handed me earlier, and I'm going to just kind of come over and stand next to you as we look through those documents.

As I understand it, these are documents that you pulled off the FDA Web site or some other Web site. Is that correct?

A. The FDA's Web site, yes, sir.

Q. What is the significance, if any, of Deposition Exhibit No. 8 to your opinions with regard to TVT-Secur?

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A. You were asking me before about MDRs. The FDA went and did MDRs, you know, up here in terms of looking at the instruments and stuff. So there's a lot of information in here about MDRs.

I would then rely on the MDA's database, looking at the different companies, so -- and I think they actually do talk about TVT-Secur in here in some places.

The highlighting is mine. They're going through, looking at -- because I think the instruments also weren't looked at, and so that was why the FDA is wanting to reclassify the instrument because that's important in terms of putting these products in. They weren't looked at as kits.

Q. And when we talk about instruments, we're talking about the instruments that, in the context of TVT-Secur, would have been provided along with the actual mesh itself?

A. That's right.

And so they weren't getting reviewed as kits where you would look at the functionality. They were -- some people -- well, Johnson -- actually, Ethicon was good. TVT, they did include the instruments in TVT to begin with, but -- and then they started kind of -- so you needed to look at the

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kit as to how the instruments worked with the -- the tape.

Q. Were the instruments for TVT-Secur brought to the attention of the FDA in conjunction with TVT-Secur's 510(k)?

A. I don't recall. I think they were in there. But the point was that the FDA was not reviewing them as kits in terms of functionality because when you look at components like that, you're supposed to look at the -- the human factors and stuff like that in using it.

And so they weren't -- they were saying in the FDA's memo in 2007, 2008, their internal discussion, how did we get to a transvaginal insertion? And so the FDA was kind of trying to backtrack, and these instruments are essential to putting these devices in blindly in the pelvis.

Q. I hate to backtrack on you and go back to something we've already covered, but I just realized I needed to cover it.

During the Garcia deposition -- I think it was on page 68 of your deposition -- you said, and I'm paraphrasing. I'm not attempting to quote you exactly, so I would ask that we all not get hung up on that.

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But you essentially said that although your disclosure didn't mention anything about MDR reporting, you did an MDR search the night before your deposition and found inconsistencies of what you believe the company knew versus what was reported in the MDRs.

You then said on page 71 that your computer wasn't working well and you were not able to print off all the reports.

And on page 73, you implied that you would continue the project and go month by month and gather the data that you needed to support your opinion.

Do you have any recollection of that testimony?

A. I remember the testimony, but I wasn't asked to go ahead and do that, so that's not in the report.

Q. Okay. So just to nail it completely solid shut, is it correct that notwithstanding your testimony and the limited comparison between the MDR reporting and the MAUDE database that you testified to -- testified about in Garcia, your earlier testimony holds true -- that is, you do not intend to provide an opinion in any federal case under this

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report that you've served in this case about an analysis or comparison between what Ethicon knew or didn't know with regard to product issue reports or complaint reporting versus what's in the MAUDE database?
A. I haven't been asked to do that.
Q. Okay.
A. And I think I was looking for trends at that time, not specific failure to report, but I was looking at the numbers that were being reported and what I knew were the reports.
Q. Okay.
A. I think they were using company documents.
Q. Have you done any analysis, or have you tried to determine the number of lawsuits that have been filed with regard to TVT-Secur?
A. No.
Q. Have you tried to determine the number of women who were implanted with the TVT-Secur?
A. No.
Q. Have you attempted to do any sort of an analysis about -- have you done an analysis of any lawyer advertising with regard to TVT-Secur?
A. No.
Q. Have you -- in your MDL reports, you have

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got some opinions about alleged problems with heavyweight small pore mesh.
Do you recall that?
A. Where are you going? Forty-eight or something?
Q. It's somewhere around paragraphs 108 to 113.
A. Okay, yeah.
Q. But do you -- and I'm not going to ask you the exact specifics.
A. Paragraph 108, is that the one you want, where I have the list? And this is -- this is coming from -- this is Ethicon's PowerPoint presentation is what this is. It is not my list.
Q. Well, that is what I wanted to ask you about.
Apart from reviewing the Ethicon documents, did you conduct any additional analysis of other documents, such as published medical literature, to reach any opinions with regard to the weight or pore size of the mesh?
A. Oh, when you saw my patent, I went and tried to get the patent. I was trying to get that.
No, nothing else.
Q. All right. So what you know -- the documents or the information that support your

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opinions with regard to the weight or the pore size of the mesh would be a function of your review of the company documents on those issues?
A. Right. Because they're not out in the other documents.
Q. Have you -- have you seen any medical literature with regard to TVT-Secur that attributes any adverse events to pore size or weight of the mesh?
MR. JONES: Objection.
THE WITNESS: No, but it's PROLENE, the mesh. And, actually, when I look at the literature, I don't see the pore size usually stated. That was why I have to use company docs.
BY MR. GAGE:
Q. Have you read Dr. Marty Weisberg's 2015 -- November 2015 deposition?
A. I have looked at it quickly, and that's why you have that. Remember, I brought that because it's not listed, I don't think, on --
Q. When did you receive that deposition?
A. I received it a couple days ago.
Q. So you received it for the first time after you had written your MDL report. Is that correct?
A. Yes, sir.

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Q. Do you intend to supplement, amend, or modify your report based on that deposition?
A. I don't think so. I haven't been asked to. I don't think I am.
Q. Have you read enough of the deposition to know whether it supports or refutes any of your opinions in your MDL Secur report?
A. It supports my opinions because I know like Health Canada wanted them to update their labeling, their TVT labeling. I have TVT labeling and they wanted them to take out mild, moderate, inflammation, so it supports my opinions.
All the changes that they made to the 2015 label they could have made at any other time. That supports my opinions, so I think it supports it.
Q. Is it fair to say that you are -- is it fair to say that the changes requested by Health Canada, in your opinion, are woefully inadequate to make the TVT-Secur IFU adequate?
MR. AYLSTOCK: Objection to form.
THE WITNESS: Well, I don't -- I mean the bottom line --
BY MR. GAGE:
Q. Let me rephrase it.
A. Yeah.

Q. Is it your opinion that the -- that the recommendations from Health Canada are inadequate to make the TVT-Secur IFU adequate?
A. Well, the Canadian came after the TVT-Secur was off the market. It's the TVT family, so if we talk about it in the family, it's still an inadequate label. I think that's what you're asking me. Do I think it's still an inadequate label.
Q. I could ask it --
MR. AYLSTOCK: I think we're over the time.
MR. GAGE: Let me just ask her a couple more.
MR. AYLSTOCK: Okay.
MR. GAGE: Because I want to correct that.
BY MR. GAGE:
Q. Is it your opinion that if Ethicon had made the changes to the TVT-Secur IFU that Health Canada recommended when the device was first launched on the market, that that would still not make the TVT-Secur IFU adequate, in your opinion?
A. Right, it wouldn't be adequate. It was not adequate because the changes that were made are fairly minor.

It's still not -- in terms of the TVT-Secur, the label is not adequate for TVT-Secur.
Q. Have you -- have you looked at any of the documents?
A. Let me clarify. It would be better than what they launched it with, but it is not adequate. It still wouldn't be adequate today.
Q. Okay. All right.
MR. GAGE: I understand counsel is calling me on my time. So like I'm sure they'll say at every deposition, if I were allowed more time, I would ask more questions, but as a understand it, I've got a hard stop at three hours.
So the only thing I'll ask counsel on the record before we go off is we do have to circle back and close some loops on some things, but I think we've all agreed to work in good faith to get that done.
MR. JONES: Indeed.
MR. GAGE: Thank you. Deposition is terminated.
(Deposition concluded at 5:06 p.m.)

C E R T I F I C A T E

I, ALISA SMITH, Registered Professional Reporter, Arizona Certified Reporter, do hereby certify that, pursuant to notice, the deposition of SUZANNE PARISIAN, M.D. was duly taken on March 8, 2016, at 1:34 p.m., before me.
The said SUZANNE PARISIAN, M.D. was duly sworn by me according to law to tell the truth, the whole truth, and nothing but the truth and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me.
I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

_____

Alisa Smith, RPR, AZ CR 50712
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ACKNOWLEDGMENT OF DEPONENT

I, SUZANNE PARISIAN, M.D., do hereby acknowledge that I have read the foregoing pages, 5 through 155, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

SUZANNE PARISIAN, M.D. DATE

Subscribed and sworn to before me this
_____ day of _____, 20____.
My Commission expires: _____

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Notary Public

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